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Maintaining physical readiness to meet demands of combat conditions is of utmost importance for active duty military personnel. As growing numbers of women of childbearing age enter active duty military service, the numbers of pregnancies among female military personnel will also increase. Thus, understanding the impact of pregnancy on subsequent fitness of postpartum active duty women becomes imperative. This project will describe the pattern of maternal weight loss after delivery in a large group of active duty and military dependent women, compare differences in weight loss by maternal characteristics, and identify characteristics of women who are most likely to become permanently overweight or obese as a result of childbearing. The study group will include 4000 women who bring their infants for pediatric care at the Naval Medical Center, San Diego. Postpartum weight will be measured at intervals ranging from 3 days to 12 months after birth. Data on prenatal factors, lifestyle behaviors, physical activity, work and other maternal characteristics will be collected by questionnaire and through abstraction of medical records. Analysis of these data will provide scientific evidence on which to base weight standards for postpartum active duty women.

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FOREWORD

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Barbara Abram 10/20/97

PI - Signature Date

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INTRODUCTION

Maintaining physical readiness to meet demands of combat conditions is of utmost importance for active duty military personnel. All branches of the military assess body size as a major indicator of fitness. During the last 20 years, the number of women on active duty in all services increased almost five-fold, from 2.5% in 1973 to 11.5% in 1992. As growing numbers of women of childbearing age enter active duty military service, the numbers of pregnancies among female military personnel will also increase. Thus, understanding the impact of pregnancy on subsequent fitness of postpartum active duty women becomes imperative.

During an average successful human pregnancy, the mother increases her body weight by 20% or more. There is strong and consistent scientific evidence that this weight gain plays an important role in ensuring a healthy infant. However, relatively few studies have addressed maternal weight loss after delivery and none have been conducted in populations of military women. Nonetheless, military women are required to return to active duty 6 weeks after delivery, in good physical condition and in uniform. Although studies in civilian populations suggest that it may take as long as a year to return to prepregnant body size,(1, 2) women in the military are expected to achieve weight and fitness standards much sooner than this: in the Navy and Marine Corps they are required to achieve weight and fitness standards within 6 months after delivery; the Army exempts women from standards for "the period of convalescent leave after birth," and the Air Force expects compliance by 3 months after delivery. Rehabilitation (comprised of a low fat diet and exercise regime) is required of women who fail to meet these standards, and if women remain outside acceptable ranges, they are subject to discipline or dismissal.

This project directly addresses the research area "Major Factors Affecting the Health or Work Performance of Military Women: Gynecology and Reproductive Health: the scientific basis for pregnancy and postpartum policies...how long to allow for returning to weight and physical fitness that meet service standards" found on page 39 of the Institute of Medicine's 1995 report Recommendations for Research on the Health of Military Women. The same issue falls under Physical Standards Linked to Occupations, "The scientific basis for physical standards" on page I-6 of the September 15, 1995 Broad Agency Announcement for Defense Women's Health Research.

The purpose of this project is to describe the pattern of weight loss during the first year after delivery in a large study group of active duty and military dependent women, to compare differences in weight loss by maternal characteristics, and to identify characteristics of women who are most likely to become permanently overweight or obese as a result of childbearing. This information will contribute to the development of more relevant standards which reflect the experiences of women who will return to acceptable levels of weight and fitness on their own, and thus could reduce the number of women who require formal rehabilitation, and the possible stresses that it may impose. Information on common predictors of excessive and permanent weight retention could allow earlier identification of women at risk, with the potential for prevention, for example by encouraging an appropriate diet and increased levels of physical activity during pregnancy or earlier after delivery. There is no question that obesity increases the risk of overall mortality and morbidity from serious medical conditions such as cardiovascular disease, diabetes, hypertension, and some forms of cancer.(3, 4) Therefore, addressing weight loss postpartum will be important for the long term health of the career service women as well as for military dependents.

Background

Maternal weight retention after birth A 1990 Institute of Medicine (IOM) report concluded that, after considering weight increases due to age and given an average maternal weight gain during pregnancy, average permanent weight retention is about 1 kg per pregnancy.(5) Recent studies are consistent with this estimate, reporting the average mother retains about 1.5 kg (3.3 pounds) of her pregnancy weight gain(1,2,6), although several report values as high as 3.8 kg (8.4 lb) at one year postpartum.(7,8) A comparison of 18-30 year old women who had been pregnant with those who had not over a 5 year period concluded that primaparas gained, on average, 2-3 kg more weight than nulliparas.(9)

However, focusing on the average weight retention can obscure important differences in subgroups. For example, median weight retention at 10-18 months after delivery was only 3.4 lb in the 1988 National Maternal Infant Health Survey (NMIHS), a national sample of 2845 US. women, but 25% of white women and 40% of black women retained more than 9 lb.(6) Similarly, in a study of 1423 Swedish women, after controlling for weight change with age, average weight retention at 1 year postpartum was only 0.5 kg(1 lb) but the frequency of overweight women increased from 13% before pregnancy to 21% postpartum.(1) Thus, studies of maternal weight retention must assess not only the experience of average women, but also provide information on subgroups, for example, by race, prepregnant size, or breast feeding status.

Pattern of postpartum weight loss Because of fluid adjustments that occur immediately after birth, most women lose weight quickly until two weeks postpartum, and then the rate of weight loss levels off.(5) Among mostly middle class white mothers who delivered in Wisconsin, fewer than one-fourth had returned to their pre-pregnancy weights by 6 weeks postpartum,(2) and mean weight retention at 6 weeks was 4.5 kg in 400 Illinois women.(8) Furthermore, in the Wisconsin study, only 37% of the women had returned to their prepregnancy weight by 6 months after delivery. These data indicate that maternal weight is not lost immediately after pregnancy, and additional research is needed to describe both average loss and its distribution throughout the first year after delivery.

Predictors of postpartum weight loss

Prenatal weight gain The strongest factor contributing to weight changes postpartum is prenatal weight gain.(1,2,5,6,8,10-13) For example, our multivariate study of the 1988 NMIHS found that women with normal prepregnancy body size who gained above 35 pounds (the upper limit of the current IOM recommendation for prenatal weight gain in normal weight women) were over twice as likely to retain 20 or more pounds postpartum than those who gained within the IOM guideline of 25-35 pounds.(11) This increased risk was present for both white and black mothers and persisted after adjustment for various maternal characteristics. Postpartum weight retention in this population was relatively low among white mothers who gained within the IOM recommendation, suggesting that current prenatal weight gain guidelines may provide some protection against postpartum obesity for these women.(6,11)

Race Since black mothers, on average, gain less weight during pregnancy than white mothers,(5) one would expect that black mothers would retain less after delivery. However, data from the 1988 NMIHS survey indicate that black mothers retain on average more weight than white mothers.(6) This difference persists regardless of prepregnancy body size or prenatal weight gain. Furthermore, in our multivariate study of NMIHS participants with normal prepregnancy weight-for-height, black mothers were over twice as likely to retain 20 or more pounds postpartum than white mothers.(11) This difference remained after adjustment for maternal age, parity, prenatal weight gain, infant birth weight, height, prepregnancy body size, marital status, and social class. Other recent studies reported similar findings.(9,13) We have identified no published data on postpartum weight change in mothers who were Hispanic, Asian or other races. Additional

research is clearly needed to determine factors that influence maternal weight loss after delivery by race.

Physical activity Increasing levels of physical activity is one of the hallmarks of weight management, but little is known about the impact of recreational or occupational physical activity in relation to maternal weight loss after delivery.(13) In a Swedish study, women who retained excess weight postpartum reported low levels of recreational physical activity during the year after birth, and increased physical activity was correlated significantly with postpartum weight loss.(14) In another small study of exclusively breast feeding women, maternal weight loss did not differ for mothers who undertook regular aerobic exercise between 6 and 18 weeks postpartum, compared to those who did not, although exercising mothers became more physically fit than their non-exercising counterparts.(15)

Dieting Not much is known about the impact of dieting during the postpartum period, for either lactating or non-lactating mothers.(14) Results of a study of Swedish women suggested that intentional dieting was associated with increased weight loss, while certain dietary practices (e.g., increased meal size, increased snacking, meal skipping) were associated with excessive weight retention.(15) Dieting is of special concern to women who breast feed, because while there appears to be little or no relationship between moderate changes in energy intake and milk volume, there is some evidence that a threshold exists under which the quality and quantity of breast milk may be compromised.(14)

Cigarette smoking Cigarette smoking, which is a major risk factor for poor health in general and during pregnancy, is protective against excessive weight retention postpartum.(1,2) In fact, the highest risk of weight retention may occur in mothers who quit smoking during pregnancy and do not resume postpartum.(1) This observed benefit of smoking does not offset the toxic effects of cigarettes on the health of both the mother and her baby.

Breast feeding New mothers are commonly told that breast feeding will accelerate their weight loss after birth. The basis of this advice is the assumption that fat stores gained during pregnancy are mobilized to subsidize the energy cost of lactating. However, while some studies suggest that breast feeding women lose weight faster than bottle-feeding women, many do not.(2,3,8,10,11,16-18)

Prepregnancy body size and weight history Wider variations in weight change postpartum are observed in women who begin pregnancy overweight than in lighter women.(1,10) There is also evidence that women with a history of weight cycling and dieting are more likely to retain excessive amounts of weight after pregnancy.(1, 19)

Social factors There is consistent evidence that women with lower income and lower education may have an increased risk of retaining more weight postpartum than women with higher socioeconomic indicators.(8,11) It is likely that socioeconomic differences are based on lifestyle behaviors and environmental circumstances. Other important risk factors for excessive postpartum weight retention include maternal age, parity, interpartum interval and maternal work outside the home. For these variables, study results are not consistent, suggesting the need for additional research.(20) Furthermore, the importance of adequate help and social support during the year after delivery to maternal weight changes, especially for those mothers working outside the home, has not been studied.

Gestational weight gain, fetal outcome and maternal postpartum weight retention As previously discussed, maternal weight gain during pregnancy is an important risk factor for excessive postpartum weight retention. This implies that restriction of maternal weight gain during pregnancy might be a useful strategy to promote a quicker maternal postpartum weight loss. However, maternal weight gain during pregnancy is an important determinant of fetal size at

delivery, which in turn is the most important predictor of survival and health of the newborn.(5) Reflecting this relationship, current recommendations for maternal weight gain during pregnancy are higher than ever before, especially for women who begin pregnancy at or below ideal weight for height.(5) Thus, although the major focus of this study is maternal weight after delivery, the birth weight of the infant must also be considered.(21) Furthermore, the pattern of maternal weight gain during pregnancy may play a more important role in fetal outcome than the total amount, although only a few studies have examined this issue. We have recently published a multivariate analysis of almost 3000 white women which suggests that, even when total maternal weight gain at delivery is held constant, a low maternal weight gain during the second trimester is associated with a significantly smaller infant.(22) Thus, maternal weight gain pattern appears to relate to infant birth weight, and it is also likely that the pattern of maternal weight gain may relate to postpartum weight retention. Several epidemiological studies have attempted to quantify levels of maternal gestational weight gain that promote fetal weight while reducing excessive maternal weight retention after delivery. One study concluded that for women who gain excessively, there is a "point of diminishing returns in birthweight at the expense of increasing maternal obesity."(23) Another concluded that "excessive gestational weight gain before 20 weeks gestation was associated with increased postpartum weight retention, especially for well nourished, overweight women."(24) A third study concluded that, in women with normal prepregnancy weight, excessive gestational weight gain did not greatly enhance fetal growth but did increase the risk of postpartum overweight.(12) However, none of these studies were able to examine factors related to maternal weight gain during pregnancy or behavioral predictors of maternal postpartum weight.

Technical Objectives These have not changed from those originally proposed. This project will :

1. Collect weight gain measurements and questionnaire data on 4025 women at the US. Naval Medical Center at San Diego (NMCSD) during the first year after birth.

2. Collect data on prenatal weight gain, birth weight, gestational age and other measures of pregnancy course and outcome by abstracting the prenatal medical records of study participants.

3. Use parametric techniques to summarize the sequential measurements to provide estimates of the overall pattern of maternal weight gain during pregnancy and the pattern of maternal weight loss after birth.

4. Summarize the average maternal weight change at 3 days, 14 days, months 2,4,6,9 and 12 after birth and its distribution.

5. Compare the average maternal weight change at 3 days, 14 days, 2,4,6,9 and 12 months after birth and its distribution by military status and by possible risk factors (including maternal race, parity, age, socioeconomic status, marital status, prepregnancy size, prenatal weight gain, method of delivery, breast feeding status, lifestyle behaviors).

6. Describe the prevalence of excess postpartum weight retention at 14 days, 2, 4, 6, 9 and 12 months after delivery in the entire study group, by the risk factors listed in Technical Objective 5 and by military status. We will explore the use of several different definitions of excessive postpartum weight retention for these analyses.

7. If the pattern of postpartum weight loss or excessive weight retention differs by military status, compare the distribution of risk factors by military status. Conduct multivariate statistical models to examine whether there are differences in the postpartum weight loss pattern and excessive weight retention by military status, controlling for potentially confounding variables. Conduct additional analyses to investigate which factors might explain any differences discovered.

8. If the pattern of postpartum weight loss or excessive weight retention differs by maternal race, compare the distribution of risk factors between white, black, Asian, Hispanic and "other race" groups. Further explore the possibility that race is associated with differences in weight loss or weight retention, controlling for potentially confounding variables using multivariate models. If racial differences are confirmed, stratify by maternal race and conduct multivariate analysis to examine risk factors for postpartum weight change within maternal race groups.

9. Using multivariate statistical models, test the hypothesis that a high maternal weight gain during pregnancy, especially during the first and third trimesters, will be associated with excessive maternal weight retention, after adjusting for potentially confounding variables including military status, and risk factors listed in Technical Objective 5.

10. Using bivariate and multivariate statistical models, examine how maternal circumstances (e.g. education, socioeconomic status, marital status, work, social support), and lifestyle behaviors during the postpartum period (including method of infant feeding, reported physical activity, dieting behavior, attitudes toward body size, work hours, sleep) relate to maternal change and excessive weight retention.

11. Use the results of previous analyses to attempt to identify those women who are most likely to become overweight as a result of childbearing, and to identify when postpartum (or during pregnancy) such women might be detected.

12. Use the results of previous analyses to describe the "ideal" pattern of maternal weight loss after delivery (and its percentile distributions) in women who deliver healthy babies and ultimately return to their ideal weight-for-height at 6 months, 9 months and 1 year after delivery.

BODY

Experimental Methods

Overview The design of this study will allow us to describe changes in maternal weight for the study group as a whole as well as to characterize changes over time in individual women. Eligible women who delivered an infant during the previous 12 months will contribute data at 1 to 7 points in time (between 3 days and 12 months after birth). At enrollment, and at all subsequent study visits, maternal weight will be measured and a questionnaire will be completed in the clinic. Two additional take-home questionnaires will be returned at baseline and at 12 months after birth. The weight and questionnaire data will be merged with information on pregnancy course and outcome abstracted from each participant's prenatal medical records. This final data set will be used to address the technical objectives of the project.

Study population and design We intentionally selected a sequential design to obtain our study population to accommodate routine military operations by which personnel are transferred, on average, every 3 years. If we utilized a strict prospective cohort design, we could expect to lose one-third of our cohort before completing follow-up. However, by defining our study groups according to infant age, data from women who are transferred can be utilized for the periods when they did participate, and new data from recent transfers can also be added to the study. Thus, some women will provide data at only one or two points of time (for example if enrolling at the end of their first postpartum year, or if entering or leaving the facility due to transfer, deployment, or separation). The large numbers of sequential observations available at each study point will enhance our ability to address our technical objectives. In addition, those mothers who are followed for the entire study period will provide prospective cohort data.

Participant tracking system We are selecting our study group from active duty and military dependent women who obtain routine well-baby health care for their infants at the Navy Medical Center at San Diego, California. We consider this population at the NMCSD representative of postpartum women throughout the United States who are active duty service women or military dependents, which is our target population. Our intended sample includes all women who meet the eligibility criteria described below. The actual study participants are those who are approached and enrolled in the study, and for the cohort study, those who provide follow-up data.

Our objective is to select study participants so that our findings accurately reflect the target population. The least amount of bias and error occurs when a randomized, population-based sample is drawn from a defined target population. In this case, a population-based sample is not possible because we are conducting this study in a pediatrics clinic, not the community. However, we are making every attempt to define and approach all potentially eligible women and to establish who enrolls in our study and who does not, so that we can estimate the proportion of the intended sample who actually enroll. Furthermore, we will compare those who enroll with those who do not on several demographic characteristics (specifically, age of infant and military status) to examine how well our actual study participants reflect the population source from which they were recruited.

To accomplish this goal, we have designed a Participant Tracking System (PTS) which allows us to :

1) Describe the underlying well-baby clinic client population of mothers,
2) Assess our success in approaching, screening and enrolling of potential study participants (our intended sample),
3) Describe the actual participants in the study,
4) Track the status and progress of each of the study participants, and
5) Produce routine progress and status reports on the study participants. Our ability to conduct these activities strengthens the scientific integrity of the study by providing insight into the composition of our study group.

The PTS is based on the clinic appointment schedule managed by the San Diego Naval Medical Center's computerized Composite Health Care System (CHCS) which tracks all medical appointments and related identifying informational records (but not medical chart records) for all patients at the facility. Using this system, we can examine the pediatric clinic appointment schedule for a given day and operationally know the pool of women to be approached for possible recruitment on that day. Working with personnel at the NMCSD Information Resources Management Department (IRMD), we created computer programs which produce daily files of pediatric clinic well-baby appointments, including information on the military sponsor, age of infant, and name/identification number for each mother-baby pair. Each day, our study staff print out a list which identifies mothers with scheduled appointments. Our recruiters then approach and screen possible study participants from the list, rather than selecting those who are convenient or depending on women to volunteer. We expected that this list would serve as an accurate database of the universe of women attending well-baby appointments each day.

However, upon implementing the system, we discovered that at least 20% of women who bring their infants for well-baby visits are not on the list (due to last-minute appointments, for example). Furthermore, it became evident that some mothers of infants from our well-baby population were willing to enroll in the study during non-urgent appointments, rather than waiting until their next well-baby appointment. To ensure that we offer study participation to every potentially eligible mother, we have modified our approach. Originally we attempted to approach only women on our list. Now our recruiters circulate throughout the clinic waiting room so that they can approach, describe the study, and screen every woman with an infant. Originally we only tracked those women who we were able to approach. Now we have developed a Daily Tally

System so that our recruiters can account for every mother on the appointment list and add those mothers that they encounter who were not on the list. This provides an accurate report of daily recruitment activities. Finally, we originally depended on the daily download of CHCS records to provide our universe of well-baby mothers. We subsequently learned that at the end of each day, the CHCS record of pediatrics appointments is corrected to reflect "same day" appointments, cancellations, no-shows and well-baby appointments that were booked in acute appointment time slots. It is this "post-appointment adjusted" database that will serve as the basis upon which the study participants are compared with regard to their being representative of the universe of clinic well-baby mothers. The women making well-baby visits who are not on the day's printed list of appointments and are not approached by our field staff can still be identified. This happens through either the post-appointment download or at the time of their next regularly scheduled well-baby visit. In this way, the participant database is either adjusted by the post download operation or ultimately self-adjusts over time as women return to the clinic. A schematic of the system is shown in Appendix A and a copy of the Daily Tally Sheet is included as Appendix B.

Eligibility Criteria Our major recruitment activities during this start-up phase of the project have concentrated on the well-baby clinic. Based on input from our pediatric collaborators at the NMCSD, we have made some minor changes in the eligibility criteria originally proposed. Our current eligibility criteria include:

1. Mother bringing her infant to the East or West Pediatrics Clinic for routine well-baby care or non-urgent medical visits. Routine well-baby care is provided to infants at ages 3 days, 14 days, and months 2,4,6, 9 and 12. Mothers with adopted infants are excluded. We also excluded mothers utilizing the Continuity Pediatrics Clinic, which cares for a high proportion of sick and disabled children. This decision reduces our need to screen large numbers of mothers who are ineligible due to their infant's condition (refer to criteria #2), although we recognized that it systematically excludes a few eligible mothers with healthy babies. The Continuity Clinic is not included in our denominator reflecting the Participant Tracking System used to define our eligible population.

2. Mother's infant spent less than 96 hours in the neonatal intensive care unit. We originally planned to exclude twins or any infant who had received neonatal intensive care. However, our Naval collaborating pediatricians felt that we would be losing a large number of healthy infants in our target population by excluding any infant who received neonatal intensive care, because many of these babies are perfectly normal after discharge. The cut-off they selected appears to work well in identifying infants with serious, long-term medical problems. Furthermore, although the original proposal planned to eliminate mothers with twins, we chose in include them based on the pediatricians' recommendations.

3. Mother can speak and read English fluently.

4. Mother or mother's sponsor is on military active duty.

5. Mother is not currently pregnant.

6. If the infant is a newborn, mother plans to return to the NMCSD's East or West Clinic for well-baby care. This ensures that we obtain a maternal weight measurement at least 2 months after birth. Although maternal weight at the two newborn visits may be an important predictor of long-term weight change, and is thus worth measuring for our cohort study, mother's weight at 3 days or 10-16 days is not an important outcome in its own right.

Recruitment

Overview and Staffing The research consulting firm, Freeman, Sullivan & Company (FSC) has been hired as a subcontractor (as described in the original proposal) to manage field operations in San Diego. The FSC staff work closely with the University of California, Berkeley (UCB) staff and the Principal Investigator to maintain scientific integrity. In our original proposal, we planned to hire one or more nurse-recruiters who would rely heavily on the pediatrics clinic appointment secretaries and medical staff to "passively recruit" our study participants. Although the response of the NMCSD Pediatrics staff has been overwhelmingly enthusiastic and cooperative, the setting is fast-paced and too chaotic to depend on this system. It became obvious that this approach would produce essentially a volunteer sample, which is likely to be extremely biased. We therefore have developed a much more labor-intensive recruitment process which is described below.

To be more attractive to our potential participants, we gave the study a new name, the "ABC Study", which stands for "After the Baby Comes". We introduced the study informally to each individual member of the clinic staff, and formally through two presentations to the pediatrics and combined pediatrics/obstetrics staff conferences, and meetings with clerical and corpsmen staff. The pediatrics clinic has been repeatedly stocked with ABC (After the Baby Comes) study pamphlets, and we are attempting to gain permission to develop attractive recruitment posters to be hung in the clinic. The extensive challenge of developing study protocols in the Pediatrics Clinic has precluded our ability to specifically address recruitment of pregnant women so far. However, we recognized that reaching women before delivery may enhance our enrollment, especially of active duty women, and we are now beginning to explore methods for reaching them. For example, we have been promised that nurses in the Active Duty Women's Prenatal Clinic at the 32nd Street Clinic on base are willing to introduce the study to all active-duty pregnant women during their 28 week antenatal visit. According to Dr. Tipton, our Navy Perinatalogist, it is unlikely that this personalized attention will be possible in the busy NMCSD antenatal clinics, but other approaches, including posters and special brochures, are invited. In addition, we encourage our staff in San Diego to participate in functions that may help advertise the ABC Study. For example, October is "Child Health Month" and the Naval Medical Center has a month-long festival. We will be participating on October 24th and October 31st, by setting up a booth displaying various types of literature and other items pertaining to the ABC Study.

The ABC study has an office located in the pediatrics clinic at the NMCSD. Rhonda Dittmar, a registered pediatric nurse with extensive clinical experience at the NMCSD clinic and hospital, is the field supervisor on site in San Diego. She supervises recruiters and coordinates project procedures with the clinic staff, including assessment of recruiter quality assurance, scheduling, and ensuring efficient productivity. Aside from being responsible for managing the recruiting and follow-up processes, the field supervisor is responsible for other items, which are included on Daily and Weekly checklists (Appendix C), which cover daily operations and procedures for shipping the paperwork to FSC in San Francisco for processing, downloading appointment lists, and running back-ups of the Participant Tracking System.

Currently, we have 7 recruiters on staff in San Diego, who are responsible for enrolling eligible participants in the East and West clinics at the Naval Medical Center. Our staff covers the clinic Monday through Friday from 0730 to 1800 and Saturday from 0800 to 1200. Since most of the appointments are scheduled for early morning, we have two recruiters covering the clinics from 0730 to 1230. The second shift, which is from 1030 to 1530, and our third shift, which is from 1300 to 1800, are each covered by one recruiter. The field supervisor also recruits during high volume appointment times.

All ABC staff are readily identifiable in the clinic by their ABC study lab coats and large, colorful identification tags. All ABC staff have been extensively trained in study procedures and to

the extent possible, have been integrated into the daily operations of the Pediatrics Clinic. The field supervisor and the recruiting staff in San Diego are employed by FSC in San Francisco. Virginia Blazier, who is in the FSC San Francisco office, is responsible for managing the staff operations in San Diego.

Recruitment Process The recruiting process is as follows:

· A copy of the daily appointment list is printed for each recruiter scheduled for the day, by the field supervisor. The appointment list identifies the well-baby appointment times, whether the mother is active duty, the baby's name & DOB (date of birth), the mother's name, the sponsor's name, physician's name, the well-baby visit number and the status of the mother in relation to participation in the ABC Study (i.e. participant, ineligible, soft-refused, contact later, refused previously, etc.).

· The recruiter identifies the appointments scheduled during their shift times and identifies whether the appointments are in the East or West Clinic by checking the physician's name on the appointment list.

· The recruiter checks the log book for any procedural changes or new information regarding the ABC Study. (The log book is used by the field supervisor to communicate changes to all recruiters.)

· The recruiter approaches and screens for eligibility each woman who enters the clinic after the woman checks in for her appointment (see Screening Form, Appendix D). The recruiter tracks the approaches by using a Daily Recruiter Tally Sheet, Appendix A. The tally sheet enables us to track the type of appointment (well-baby / acute), whether the participant was on the daily appointment list, and the outcome/disposition of the approach.

· The recruiter reviews the consent form (Appendix E) with the eligible participant. Two copies are signed, one of which is provided to the participant.

· The participant signs the Medical Records Release Form.

· The recruiter gives the participant an ABC Welcome Letter, Participant Information Summary, and an ABC Staff business card.

· The recruiter instructs the participant to complete a clinic questionnaire and measures her weight and height.

· If the baby is 2 months or older, the recruiter gives the participant a baseline questionnaire to take home, complete, and mail to the San Francisco office.

· The recruiter briefly explains the follow-up process pertaining to the participant's next well-baby appointment. In particular the recruiter advises the mother to identify herself as an ABC mother whenever she checks into the clinic, and to expect to wear an ABC sticker at every appointment. The recruiter also finds the infant's medical record and affixes a small ABC sticker on it to support follow-up.

· At the end of the shift, the recruiters turn in their Screening Forms, enrollment packets and Tally Sheets to the field supervisor.

Follow-up Process The follow-up process is as follows:

The follow-up process for the enrolled participants depends on the same Participant Tracking System used for recruitment. When the daily appointment list is downloaded, participants who are already enrolled are marked as study follow-up visits on the list. Actual follow-up is accomplished with the assistance of Navy clinic personnel, particularly the check-in clerks and the corpsmen, in conjunction with the ABC study staff. Check-in clerks have been trained to give each ABC participant an ABC sticker to wear upon check-in. We have found that this is very acceptable to the mothers. Participants often identify themselves as ABC participants upon check-in, and if they don't, clerks are alerted by the ABC stickers which are affixed to the infant's medical charts when the mother enrolls in the study. The sticker on the mother alerts the corpsmen to weigh the mother and provide her with a clinic questionnaire; the stickers also alert study staff that the woman is already a participant and therefore requires follow-up data collection rather then recruitment.

· Each morning, the ABC study daily appointment list is reviewed to identify the names, scheduled visit time and clinic location for each follow-up participant. Our system also allows us to follow those women with unexpected clinic visits. The field supervisor prepares a Daily Follow-Up Tally Sheet (Appendix F), pre-recording all the scheduled follow-up visits expected for the day. At the end of the day, the disposition of each visit, including those not originally on the list, as well as the measured weight for each mother, is recorded on this sheet, which serves as a record of follow-up activities for that day.

· The field supervisor checks the medical charts, for the follow-up visits for the day, at the check-in desks to make sure the charts already have an "ABC Study" sticker affixed to them. A sticker is put on the folder if one is not already there.

· When the participant checks-in and is recognized by the check-in clerk as an ABC participant, she is given an "ABC Mom" sticker to wear and a clinic questionnaire to complete. To remind the participants to identify themselves, a sign is posted on each of the check-in counters.

· The corpsman/nurse, who is responsible for taking the baby's measurements, will recognize the mother as a participant in one or more of the previously described ways. The corpsman/nurse weighs the participant and records the weight on the clinic questionnaire, as well as the baby's measurements (upon the request of our collaborating pediatricians), and then returns the questionnaire to the participant to complete. The completed questionnaire is either collected personally by an ABC staff member or placed by the mother in one of several designated ABC drop-boxes (which are emptied several times a day) in the clinic waiting areas.

During the course of the day, the field supervisor routinely monitors both clinics to ensure that follow-up activities are implemented appropriately.

Data Collection

Data for this project are collected from 3 different sources: 1) Measurements of weight (and one height measurement), 2) Questionnaires, Clinic and Take-Home, and 3) Medical Record Abstraction.

Weight and Height Maternal postpartum weights are measured on a calibrated, digital scale. The mother wears light clothing and no shoes. Each mother is weighed twice, and if the two weights disagree by more than 0.1 kg, the mother is weighed a third time. Maternal height is measured at the first visit using a stadiometer. A minimum of two height measurements are taken to ensure accuracy. The majority of the measurements are taken by clinic corpsmen who have been formally trained to follow specific protocols. Some measurements are also taken by ABC study staff members who have been similarly trained. A quality assurance protocol is in place which rechecks the accuracy of the measurements on a routine basis, and provides retraining as needed.

On request of our collaborating pediatricians, we are also recording and entering infant weight, length and head circumference at each visit.

Clinic Questionnaires We are using three different clinic questionnaires:

3-7 Day Clinic Questionnaire: A short questionnaire consisting of ~10 questions given to mothers enrolled at the 3 day weight check. We intentionally kept this instrument short to minimize participant burden as women of newborns are usually extremely exhausted and overwhelmed.

10-16 Day Clinic Questionnaire: A slightly longer questionnaire (~30 questions) given to mothers at the 2 week well-baby check. Again we kept it as short as possible, given our concerns about participant burden.

2-12 Month Clinic Questionnaire: This questionnaire is self-administered at each well-baby or non-urgent care appointment at 2 months postpartum or whenever the mother enrolls. Although it consists of ~ 50 questions, women easily complete it in about 10-15 minutes, and because their usual clinic waiting time is much longer, it has not been a problem.

Take-home Questionnaires We are using three different questionnaires. The Baseline Questionnaire is administered at or after 2 months postpartum and the Follow-up Questionnaire is administered when the infant is 12 months old. The women are provided with self addressed and postage paid return envelopes when they receive the take-home questionnaires. Women mail their completed questionnaire to our San Francisco office and receive $10 for each questionnaire returned.

The Baseline Questionnaire asks questions about family history, prenatal weight gain, smoking, physical activity, dieting practices and work during and after pregnancy and sociodemographic data. Depression and body image scales covering the previous seven days are also included.

The Follow-up Questionnaire asks women to reflect upon the past year in relation to their diet, physical activity, work, dieting behavior and infant feeding practices. It also includes a depression scale for the previous seven days.

The 12 Month Enrollment Questionnaire is designed specifically for women who enroll at the 12 month visit. It combines the most relevant questions from both the Baseline and Follow-up questionnaires to minimize participant burden.

Questionnaire Content

Appendix G displays the variables studied, and Appendix H contains a copy of the 2-12 month Clinic and Baseline Take-home questionnaires (other questionnaires are available upon request). All variables listed have been included because there is evidence that they may influence maternal weight after delivery. Whenever possible we have used validated instruments and standard definitions to be consistent with other studies. This approach is summarized below.

1) Depression: is measured using the Center for Epidemiologic Studies-Depression Scale (CES-D) because it has been validated in the scientific literature (25) and it has been used in other large recent studies of women (the National Institute of Aging's SWAN: Study of Women Across the Nation study, WIHS: Women's Interagency HIV Study, funded by several institutes within the National Institutes of Health, and the Centers for Disease Control's HERS: HIV Epidemiology Research Study). Furthermore, this instrument consists of 20 short questions that are easy to understand and it is easily self administered. We considered scales designed specifically to

measure postpartum depression, particularly the Edinborough Postnatal Depression Scale (26), but decided that the CES-D was a more useful assessment of mood for this population.

2) Lactation: To measure intensity of lactation, we developed an infant feeding question for the clinic questionnaire. It is based upon the recommendations by the Institute of Medicine.(27) Our question differentiates between exclusive breast feeders, bottle feeders and levels in between these extremes: partial and token breast feeders. Questions about other foods and juices fed to the baby are also included in the clinic questionnaire. To measure duration of breast feeding, we also included questions in the 12 Month Follow-up questionnaire to determine when mothers began to wean their infants and stopped breast feeding completely. We also investigate the barriers to breast feeding and the reasons women stop. The series of possible responses compiled from other studies (28) serve as the basis for this question.

3) Body Image: We conducted an extensive review of the literature addressing measurement of body image perceptions and identifying people with eating disorders. Because many of the questionnaires were outdated or extremely long and detailed, we chose to develop 4 very short questions about weight, shape, eating and appearance that generally measure the amount of time a mother thinks about these issues, using the same response categories in the CES-D (depression) scale.

We also chose to include a set of 9 silhouettes of women ranging from quite thin to very obese. These silhouettes have been validated in the literature (29) and have been used successful to measure body image of pregnant women.(30)

4) Dieting Practices: We compiled an extensive list of dieting practices based primarily upon questions utilized in the National Center for Health Statistics studies and other sources.(31,32)

5) Physical Activity: We worked very closely with our consultant exercise physiologist to develop a combination of validated scales to measure current overall activity and work-related activity.(33-38) These questions were then adapted to reflect recalled physical activity during pregnancy.

6) Active Duty Women: After meeting with active duty women (both postpartum mothers participating in our pre-tests and female pediatric staff), we developed a series of questions related to physical readiness test concerns and physical training requirements.

7) Social Support/Deployment/Spouses: We developed a series of questions to estimate social support because we did not identify a useful source of published questions after consulting with expert psychologists here at UCB. To our surprise, during the pretest, women universally stressed the importance of measuring spousal deployment as a potential factor in maternal postpartum weight. Therefore, we added questions to measure the duration of deployment during the baby's first year.

7) Dietary Intake: The Health Habits and History Questionnaire (HHHQ-Block), a semiquantitative food frequency instrument developed and validated by Gladys Block at the National Cancer Institute and here at UCB, will be used to assess dietary intake during the 6-12 months postpartum period. This self-administered questionnaire is highly respected and used in numerous studies throughout the United States to measure diet and health.(39)

Pre-testing of instruments During the first three months of the project, the study questions were pretested with approximately 30 active-duty and dependent mothers with infants of

the ages to be included in this study at the NMCSD to ensure that the instruments are understandable and acceptable. Based on results of these pretests, the proposed data collection procedures and questions were revised as necessary. In addition, we have closely examined the questionnaires completed by participants early in the study and made some minor changes in the final questionnaires to clarify the questions as needed.

Medical Record Abstraction The goal of medical record abstraction in the ABC Study is to collect information from the medical records of participants regarding their prenatal course and delivery. This information will:

1) Provide demographic data regarding the mother,
2) Allow calculation of the gestational age of the infant at the time of delivery,
3) Allow calculation of the total weight gain and pattern of weight gain during pregnancy for the mother and
4) Provide information regarding the type of delivery, complications, and birth weight of the infant(s).

This information will be used to examine the relationship between prenatal events and events surrounding labor and delivery and their possible impact on the health and fitness of mothers in the first year following the delivery.

For each study participant, information on prepregnancy weight reported at the first prenatal visit, all prenatal weight measurements and their dates, infant birth weight(s), gestational age at birth, first ultrasound measurement (to confirm gestational age), rank (of mother or her sponsor), race, age, parity, and route of delivery and cigarette smoking will be abstracted from the obstetrical medical records. Variables included are displayed in Appendix G in the Medical Records Abstraction (MRA) column. The organization of the medical records will serve as the basis for the development of data entry software designed specifically for this project. A complete protocol for record abstraction has been developed and pretested. To save time and resources, data will be directly entered from the medical record into a laptop computer in the Medical Records Library of the NMCSD. The software will include checks for logical consistency and edit checks to identify errors when the data are entered. We have worked closely with the Medical Records staff at the NMCSD to develop a system for obtaining the required records.

We use two different versions of a medical release form. We worked directly with the Head of the Inpatient Medical Records at the NMCSD to design a release form that meets the institution's specifications exactly for infants delivered at NMCSD. We anticipate that 90% of our cohort will deliver at NMCSD. A more generic release form that requests copies of prenatal, labor and delivery information, is sent to hospitals for infants delivered at other institutions. Copies of these records will be sent to our San Francisco office and abstracted by UCB staff and stored in locked cabinets to preserve confidentiality.

Data Management Each week ABC study enrollment packets for new participants, Screening Forms for all other women approached who did not enroll, and follow-up clinic questionnaires are mailed from San Diego to San Francisco. This information is reviewed, edited and data-entered (double-keyed and verified). Specific processes for data editing and data entry are currently being finalized. To address our technical objectives, we will merge all questionnaire data, weight and height measurements, infant size measurements, data abstracted from the medical records and selected variables from the Participant Tracking System.

Quality Control Quality Control of clinic operations is assured in several ways. A detailed manual of all study operations has been developed and updated regularly. All staff have been formally trained, and updates to protocols are implemented systematically and their impact is evaluated regularly. The Operations Manager at FSC in San Francisco oversees the entire San Diego office using a well-defined reporting system of checklists, logbooks, tally sheets, etc. as described

previously. She is in daily communication by phone and email with the San Diego staff. Each recruiter's performance in approaching and enrolling study participants is monitored twice per week by the nurse-supervisor using a specially-developed form which measures accuracy, procedural adherence, knowledge of the study, efficiency in time management, and recruiting techniques. The nurse supervisor is also responsible for formally training the corpsmen to correctly measure and record weight and height, and to assess the accuracy and reliability of these measurements on a regular basis. Quality control forms are in Appendix I, and our training manual is available on request.

Medical record abstraction will be verified by retrieving a randomly selected sample of medical charts and comparing the original data against entered data. Each abstracted data file record will contain the initials of the field staff abstractor and formal evaluations will be given to each abstractor based on the outcome of these reviews.

Data Analysis Data will be analyzed by the research team at The University of California, Berkeley (UCB) with substantial input from the co-investigators at the NMCSD. The raw data will be entered into a database file and cleaned prior to analysis. Our data analysis plan has not changed from that described in the original proposal, and will not be repeated here because our emphasis in this first year has been to develop and implement study protocols to produce the highest quality data for analysis. With our field operations established and running smoothly, we intend to shift our focus toward data analysis strategies in the coming year.

Results and Discussion: Progress to Date and Preliminary Results

Table 1 displays the results of recruitment efforts for the ABC Study from May 21, 1997 when we began our pilot phase through October 3, 1997. The "Actual Appointments Listed" column (n=2191 expected well-baby mothers) indicates the number of expected appointments generated at the beginning of each recruitment day by our Participant Tracking System. Using the sponsor social security number for each woman, the PTS eliminates duplicate counting of the "universe" of women attending well-baby visits at the clinic. Also, women who are recruited and who are not on the appointment list are added to the PTS. Using data from our Daily Recruitment Tallies, we estimate that 88% of the women on the printed appointment list actually appeared in the pediatrics clinic as scheduled (Estimated Probable Show column, n=1928). Again, based on our Daily Recruitment Tallies, we estimate that an additional 208 women who were not on our PTS-generated list also came in for well-baby visits. Thus, we estimate that our intended sample numbered 2136 new mothers (Estimated Probably Potential column) during our data collection period.

As previously discussed, our objective is to approach and screen every mother in our intended sample. The Screening Activity Column in Table 1 shows that during the pilot phase, we estimate that we approached about 60% of our intended sample, however, our approach rate has increased progressively to 75% in August to 85% in September to 95% during the first week in October. Similarly, the percent of those we approached that we were able to screen increased from 48% during the pilot to 89% in August and September, and our Daily Recruitment Tally System indicates that we actually screened 100% of the intended sample during the first week in October. We believe that the post-appointment download data from CHCS during the early part of the study (May-August) may have missed accounting for some portion of the no-shows and cancellations. Working with IRMD we have revised the post download programming and are now in the process of adjusting the database. This adjustment may improve the reported "percent of women approached" by slightly reducing the denominator for each of those time periods. Table 2 displays the outcome of our screening activity based on the unadjusted Participant Tracking Database. Overall, n=204, or 20% of the women screened to date did not meet the study eligibility criteria. Of the remaining eligible mothers screened, about 6% chose not to participate, and an additional

ABC Study Clinic Population Recruitment Report

Period from May 21, 1997 through October 3, 1997

Table 1: ABC Study Recruitment Activity Divided into Four Study Phases T1-T4

Time Period				Weeks Per Time Period	Clinic Population Available				Screening Activity				Enrollment Statistics			
	from	to			Actual Appts. Listed	Estimated Probable Show 86%	Estimated Probable Off-List * 50%	Estimated Probable Potential (Total)	Estimated Approach Rates	Estimated Approached (T4=Actual)	Actual Number Screened	Percent of Approached Screened	Actual Number Enrolled	Percent of Approaches	Percent of Screened	Number Enrolled per week
T1	21-May	3-Aug	*Pilot Phase*	10.5	1405	1236	0	1236	0.60	742	354	48%	232	31%	66%	22.1
T2	4-Aug	30-Aug		4	417	367	46	413	0.75	310	276	89%	159	51%	58%	39.8
T3	31-Aug	27-Sep		4	307	270	135	405	0.85	344	305	89%	184	53%	60%	46.0
T4	29-Sep	3-Oct	*Part month*	1	62	55	27	82	0.95	78	78	100%	47	60%	60%	47.0
			TOTALS:	19.5	**2191**	**1928**	**208**	**2136**	-	**1474**	**1013**	-	**622**	-	-	-

* Off-List approaches started in the last week of T2

Table 2: ABC Study Screening Dispositions During Four Study Phases T1-T4

Time Period			Outcome of Screening Activity									Military Status of Enrollees				
	from	to	Number Screened	Number Ineligible	Percent of Screened	Number Refused	Percent of Screened	Number Postponed Recruitment	Percent of Screened	Number of Enrollment Pending	Percent of Screened	Actual Number Enrolled	Number Active Duty Enrolled	Percent of Enrolled	Number Dependents Enrolled	Percent of Enrolled
T1	21-May	3-Aug	354	46	13%	23	6%	23	6%	30	8%	232	64	28%	168	72%
T2	4-Aug	30-Aug	276	76	28%	18	7%	23	8%	0	0%	159	24	15%	135	85%
T3	31-Aug	27-Sep	305	66	22%	20	7%	35	11%	0	0%	184	37	20%	147	80%
T4	29-Sep	3-Oct	78	16	21%	4	5%	11	14%	0	0%	47	13	28%	34	72%
		TOTALS:	**1013**	**204**	20%	**65**	6%	**92**	9%	**30**	3%	**622**	**138**	22%	**484**	78%

9% asked that we discuss the study again at their next well-baby visit. Thus, of the 809 women who screened eligible since the study began, we have enrolled 622 women, which represents an overall response rate of 77%. Our current enrollment is proceeding at about 47 participants per week.

The major focus of this study is the weight loss pattern of active-duty service women. Of the 622 women currently enrolled, 138 or 22% are active-duty mothers. This proportion is very close to the 20% of participants that we estimated, based on birth-record data from NMCSD Obstetrics unit, in our original proposal. Our Participant Tracking System also indicates that 89% of the mothers delivered at NMCSD, and that approximately 57% are first time mothers, 29% have one child in addition to this new baby and the remaining have more than 2 children. Table 3, The Participant Description Report, also shows the number and percent of enrollees by infant age from birth through nine months. We have only begun recruiting one year olds this month.

Our Participant Tracking System does not provide details on other characteristics of the mothers, but we are able to report some findings on the first 223 enrollees. We cannot, of course, reach any conclusions based on this very small and preliminary sample, but present these data to illustrate what we know about the group of participants very early in the study.

This small number of cross-sectional observations includes mothers of infants from birth to 9 months. Sixteen percent (n=34) of these women are active duty, and 91% of them reported that they were working or going to school. Among the 168 mothers who are military dependents, only 27% were working or going to school. The racial composition of the entire group is 58.6% (n=130) white, 9.9% (n=22) Black, 18.5% (n=41) Hispanic and the remainder are Asian, Filipino, Native American, mixed or other. Among active duty mothers, about 12% are Black and 15% Hispanic. Only 5% of all mothers have less than a high school education and 51% have attended college. Sixty three percent of the participants report family incomes less than $2500 per month. Virtually all (96%) are married.

The mean reported prepregnancy weight-for-height (represented here by the body mass index (BMI)=weight (kg)/height (m^2)) is about 26, which represents the upper limit of the "normal" BMI range according to the Institute of Medicine. Prepregnancy BMI did not differ by military status, but active duty women are about 3.4 cm taller and their prepregnancy weight 3.8 kg heavier than dependent mothers. In this limited group of participants, the mean reported pregnancy weight gain is about 16 kg (19.3 kg in active-duty women and 15.4 kg in military dependent mothers) Therefore, the active duty women would have about 4 kg more to lose postpartum than the dependent mothers. The measured postpartum weight data for the group as a whole suggest a steady, decreasing trend in mean weight-for-height as follows: 3 days after birth (BMI=29.8); 10-16 days (BMI=27.8); 2 months (BMI=26.7), 4 months (BMI=26.4), 6 months (BMI=24.6), 9 months (BMI=25.7), with little difference in weight change by maternal military status. In terms of weight management, about half the active duty mothers reported that they were attempting to eat less food and be more physically active compared to about a third of the military dependent mothers.

Table 3: ABC Study: Participant Description Report
Week ending 10/3/97

	Count	Percent	*Adjusted ** *Percent*	*Estimated Count*
Total women recruited	622	100%		
Active Duty	138	22%		
Other Children				
Not known (pre 7/24/97)	243	39%		
None	216	35%	*57%*	*354*
One	109	18%	*29%*	*179*
Two	41	7%	*11%*	*67*
Three	8	1%	*2%*	*13*
Four or more	5	1%	*1%*	*8*
				622
Clinic Questionnaire Completed				
Unknown, status pending	3	0.5%		
3 - 7 days	123	20%		
10 - 16 days	107	17%		
2 months	133	21%		
4 months	100	16%		
6 months	95	15%		
9 months	61	10%		
12 months	0	0%		
Baby delivered at NMCSD	551	89%		

** Distribution of known only. Estimated number including unknowns is based on this known distribution*

Recommendations: Assessment of Progress in Terms of the Original Statement of Work

In our original proposal, we included 11 tasks in our Statement of Work. We address only Tasks 1 and 2 (a and b) in this progress report. The other 9 Tasks directly relate to data analysis which will commence in the coming year of the project.

Task 1: Hold advisory meeting. Finalize protocol, hire staff, draft and field-test data collection methods. Begin recruiting prenatal women. (proposed months 1-3)

The process of finalizing the study protocol, developing and field-testing data collection instruments and procedures and obtaining human subjects certification for this complex study took much longer than we anticipated in our original proposal. We therefore completed Task 1 five months later than we expected. In addition to the usual methodological challenges related to initiating a large field study, we had to overcome two major barriers before we could begin data collection. First, although we began our human subjects certification procedure in September, 1996, immediately after the proposal was funded, we had to coordinate between committees at two different institutions (University of California, Berkeley, Committee for the Protection of Human Subjects and Clinical Investigation Department at the Naval Medical Center, San Diego) and we were not granted full approval to collect data from human subjects until April 15, 1997.

Second, as discussed previously, we worked very closely with the NMCSD Information Resources Management Department to create the computer programs which produce our Participant Tracking System. Unfortunately, it took until late May, 1997 to work out our agreements, write, test and debug the special computer programs needed to accomplish the data linkages, and create the data files needed for recruitment and follow-up. In fact, we are still fine-tuning our programs to respond to the data needs of the study. Because our Participant Tracking System strengthens the scientific integrity of our study, we feel the delay was worthwhile, especially given that we did not have approval from the institutional review boards to recruit until mid-April.

We have chosen to delay our advisory meeting until we have data to show our Advisory Committee. However, we have contacted some members of the Advisory Committee for expert input and responses to our questionnaires/data collection procedures on an individual basis. We plan to hold an advisory meeting when we finalize our data analysis plans, and again at the end of the project to gain input relating to interpretation of the study results.

Task 2: a. Collect data on 4000 women during the first year after birth. Recruit subjects, collect postpartum maternal weight measurements and questionnaires. Edit, code and enter data. b. Obtain/abstract prenatal medical records, enter data (proposed months 4-28)

As of 10/3/97 we have enrolled a total of 622 postpartum women into our study and we have collected follow-up data on 180 of these women. We only began to enroll mothers of 12 month old infants last week because it took longer than we expected to develop the 12-month Follow-up Take-Home questionnaire.

If we continue to enroll women at our current rate of about 47 per week, we can theoretically meet our target of 4000 women who provide cross-sectional data for at least one time point over the next 18 months. Our goal, however, is to collect repeated measurements from as

many women as possible, so we are working intensely to increase our number of enrollments now to allow time for follow-up. We recognize that we may reach a point in the study where we have enrolled such a high proportion of well-baby mothers into our study that even if our approach and enrollment rates are high, our yield of new participants will be low, and limited primarily to newborn infants. This reduction in potential new participants may be counter-balanced by new infant-mother pairs entering the clinic population through military transfers. We are also watching carefully for an impact of the introduction of a managed care approach to the NMCSD pediatric clinic. To date, managed care has not reduced the number of potential participants we can approach and enroll.

At this point, we believe that we will succeed in our original goal of enrolling a study group of 4000 participants. However, even if we fall short of our proposed sample size, we will have sufficient statistical power to test our major hypotheses for the study group at large. (Please see the discussion of sample size and power in original proposal. In that discussion, we point out that even with 4000 participants, we may not have a sufficient sample size of certain subgroups.)

Although our early recruitment efforts fell below our goals, we were able to assess our progress using our Participant Tracking System and record-keeping/observation by our San Diego and FSC staff. The information we gained through careful monitoring allowed us to quickly respond by reorganizing our field recruitment operation. In early August we hired and trained more recruiters and instituted a more labor intensive, comprehensive system for assessing the recruitment and follow-up operations. Data entry and data processing tasks formerly conducted in the San Diego field office were transferred to the San Francisco offices of FSC. This made more San Diego staff hours available for recruitment. This revised approach increased screening and enrollment rates almost immediately. The Daily Tally System we instituted in late August, combined with the electronic Participant Tracking System, now allows us to accurately monitor our intended sample, and to calculate our approach, screening and enrollment rates. We intend to continue to carefully monitor our sample on a regular basis with the goal of obtaining a reasonable estimate of how long it will take to accrue our original proposed sample size, and to assess whether there are additional approaches we can implement to achieve this goal.

Furthermore, we have put into place routine quality assurance procedures with the objective of reducing both random error and bias in both our study group and in our measurements. The variables included in our questionnaires are comprehensive and relevant, and we are certain that the data we are collecting will allow us to successfully address our technical objectives.

As our recruitment process settled into a smooth routine, the development of follow-up procedures likewise evolved. For example, affixing stickers to charts during enrollment facilitated identification of participants for follow-up visits. We can monitor the success of follow-up visits using the same tools (the PTS and Tally Sheets) that we use to assess recruitment success.

We have designed, and are now pretesting and refining, high quality protocols for editing, coding and entering data. We expect that routine data entry will commence within the next month.

The procedures for MRA have been created and are in the process of being finalized. Data entry will be accomplished by trained abstractors who enter the data using a specially designed computer program which includes data checks.

Finally, we are pleased to report that we have established a thriving and productive collaboration with our Navy co-investigators, our pediatrician, Dr. McCaffery (and Dr. Shope before he left for his fellowship), our perinatologist, Dr. Tipton, and our nurse-specialist, Captain Kohler. The successful integration of the ABC Study into the Pediatrics Clinic at the NMCSD exceeds even our most optimistic expectations. We feel confident that the ABC Study will achieve its Technical Objectives and the Tasks outlined in the Statement of Work.

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Appendix A: Schematic of Computer System Operation

Schematic of Computer System Operation

Step 1. One Week Before Appointment Date

CHCS Computer Generates the Appointments Listing for Date

Upload

"PRE" *Download*

SD Study Field Site | *New list data* | *Cumulative database*

List is matched and merged | **"PRE" Working List Produced for Date**

Step 2. 24-Hours Before or Same Day as Appointment Date

"REV" *Download*

SD Study Field Site | *New list data* | *Cumulative database*

List is matched and merged | **"REV" Working List Produced for Date**

Step 3. Day of Appointment Date

Outcome of Day Entered | *Cumulative database updated*

Step 4. X Days After Appointment Date

CHCS Computer Generates the Final Outcome Appointments Listing for Date

Upload

"POST" *Download*

SD Study Field Site | *Final list* | *Checked against database outcome listing for No Shows & Rescheduled Missed, Walk-Ins*

List is updated for appointment outcomes. | **"POST" List produced for Date with study identification numbers assigned.**

Appendix B: Daily Recruiter Tally Sheet

DAILY RECRUITER TALLY SHEET

INT ID#:	NAME:		DATE:	
SHIFT START:	SHIFT END:	TOTAL HOURS:	PROJECT #:	

ENROLLMENTS

	APPOINTMENT LIST			NOT ONAPPOINTMENT LIST			
		FSCID # / Sponsor Full SS#			Sponsor Full SS #		
		Well-Baby	Acute		Well-Baby	Acute	
	1			1			
	2			2			
	3			3			
	4			4			
	5			5			
	6			6			
	7			7			
	8			8			
	9			9			
	10			10			
							TOTAL
1 (R) Refused							
2 (L) Con. Later							
3 (N) NS/Cancel							
4 (M) Rec Missed Appt							
5 (I) Ineligible							
6 (P) AlreadyEnrolled							
11 No Longer Part.							
12 Other Than Mother							
Total Enrollments							
Total Screeners							

NOTES:

Appendix C: Daily Checklist/Weekly Tasks

DAILY CHECK LIST

Supervisor:_____ Date:_____

Project: #628/3 ABC STUDY

OPENING THE SHIFT

1._____ **ANS. MACHINE** - Check ans. machine for messages. (Opening/during shift)

2._____ **E-MAIL** - Check e-mail .(Opening/during shift)

3._____ **CHECK SCHEDULES**- Verify who and how many interviewers are coming in for the shift. Write this information on the DAILY PRODUCTIVITY REPORT sheet.

4._____ **APPOINTMENT LISTS** - Make sure the appointment list was downloaded and printed for the current day and that there are enough copies for all scheduled recruiters.

5._____ **RECRUITMENT SUPPLIES** - Make sure there are enough supplies ready for the daily scheduled hours. This includes checking and stocking bins with recruitment folders, brochures, pens etc. There should always be at least 10 pre made folders for each visit type in the bins. Also, make sure ABC table is set up and that the baby seat is out in clinic.

6._____ **DISTRIBUTE INFORMATION IN IN-BOXES**- If there are any memos or information sheets make sure each recruiter receives a copy in their IN Box. Also, update communications log if necessary.

7._____ **CHECK - IN** - Make sure scheduled employees clock-in at scheduled time and note any late or absent employees. Make sure to get reasons for tardiness and absences.

8._____ **PREP VISIT #2 FOLLOW UP** - Place 10-16 day questionnaire with follow up cover sheet in babies' charts.

DURING THE SHIFT

9._____ **CHECK MAIL**- Go to mail room and ask for mail for the ABC Study

10._____ **QUALITY ASSURANCE** - Observe each recruiter in each clinic to ensure recruiting guidelines are being followed. Number of QA reports for day = _____

11._____ **PRODUCTIVITY** - Monitor for full utilization of time and ensure production goals are met.

12._____ **RECRUITING** - Recruit when coverage is necessary due to a shortage in the hours scheduled or when there is an influx of potential participants in the clinic.

13._____ **POST DOWNLOAD** - Run the post download for 2 days before the current day. Start download and go out to clinic. Check back in 20 minutes to see if complete.

CLOSING THE SHIFT

14._____ **CHECK-OUT** - Make sure all employees clock-out at scheduled time and verify their next scheduled day and time.

15._____ **PAPERWORK** - Ensure that all individual daily paperwork has been turned in. Bundle each days folders with Daily Enrollment Report cover sheet.

16._____ **DAILY REPORT** - Prepare and e-mail Daily Status Report to Ginger at FSC/San Francisco at Blazier@fsc-research.com.

17._____ **DOWNLOAD** - Download the appointment list for a week from that day and for the following day. Make 6 - 8 copies of tomorrow's appointment list.

18._____ **COLLECT SUPPLIES** - Collect all supplies from the clinic floors and lock everything in the ABC office

WEEKLY TASKS

MONDAY:

_____ SHIPPING - Take daily batches of folders, screeners, returned questionnaires from prior week and box up to send to FSC/SF via UPS. Verify that each day is batched with a daily enrollment report and that the total is clearly marked.

FRIDAY:

_____ DOWNLOAD - Download appointment list for Saturday, Sunday, Monday and the next Friday.

_____ BACK-UP DATABASE - Back up database by clicking the icon that says "Back-up Database". Read the instructions that appear and hit enter. Make sure that the ABC database is closed before doing back-up.

_____ BACK-UP DATABASE ON DISK - Take one of the 3 rotating back-up disks and place in your a:\ drive. Then go into file manager and locate the navy1db.zip file that was created by clicking the "Back-up Database" button in either back_up1, back_up2 or back_up3. Take the one with today's date. Drag the file onto the a:\ drive. Make sure you copy the file and don't move it.

_____ EMAIL DATABASE TO FSC/SF - Take the same navy1db.zip file, with today's date, and attach to an email message. Email to rcaplan@fsc-research.com.

Appendix D: Screening Form

The A B C Study Screening Form

LISTED: YES ❑1 FSCID: 6 2 8 _____
NO ❑2

Sponsor's First Name:	Sponsor's Last Name:	Sponsor's SSN: ___-___-____
Child's First Name:	Child's Last Name:	Child's Birth Date: Mo./Day/Yr. ___/___/___
Mother's First Name:	Mother's Last Name:	Appointment Date: Mo./Day/Yr. ___/___/___

1. Mother screened: YES ❑1 NO ❑2 If NO: ❑1 Declined-contact later
❑2 Declined-don't approach again
❑3 Father/other person brought child
❑4 Other: _____

2. Active Duty: YES ❑1 NO ❑2

If YES: Branch: _____

If YES: Rank: _____

3. Number of Other Births: ❑

4. Mother's Birth Date: ___/___/___

5. ELIGIBILITY CRITERIA

Mother is currently pregnant	YES ❑1	NO ❑2
Child spent > 96 hours (4 days) in the neo-natal intensive care unit	YES ❑1	NO ❑2
Biological child who is ≤ 12 months old	YES ❑1	NO ❑2
Mother reads and speaks English	YES ❑1	NO ❑2
Well Baby Care beyond 3-7 or 10-16 days to be obtained at Balboa	YES ❑1	NO ❑2

IF Not Balboa, where (*Circle*): Mir 32ndSt. NoIsl NcareSBay NcareClr Other: _____

If any of the shaded boxes are checked, STOP. The mother is NOT ELIGIBLE.

6. Agreed to Enroll: YES ❑1 NO ❑2 If NO: Spouse deployed/TAD: YES ❑1 NO ❑2

If YES: Consent Obtained: YES ❑1 NO ❑2

7. Balboa Delivery: YES ❑1 NO ❑2 If NO: Name and location of birth hospital:

Name: _____

City, State: _____

8. Recruitment Status Code: ❑

Mailing Address:	
e-mail address:	Copy of Results: YES ❑1 NO ❑2
Telephone #: Daytime: Evening:	Best Time to Call:

Screening Form: - 08/20/97

ABC STAFF ID# ___ ___

Appendix E: Consent Form

NAVAL MEDICAL CENTER
SAN DIEGO, CALIFORNIA 92134-5000

CONSENT BY A SUBJECT FOR VOLUNTARY PARTICIPATION IN A CLINICAL INVESTIGATION (RESEARCH) STUDY

1. I, _____, have been asked to voluntarily participate in a research project entitled, **"Postpartum Maternal Weight Changes: Implications for Military Women"**, also known as **"After the Baby Comes: The ABC Study"**, being conducted at the Naval Medical Center, San Diego by medical researchers from the Departments of Ob/Gyn and Pediatrics in collaboration with the School of Public Health at the University of California at Berkeley.

2. The objectives or purposes of this research project are to describe how maternal lifestyles, body weight and fitness change in active-duty military women and in family members of active-duty servicemen during the first year after they each gave birth to a baby. We are also studying how the amount and pattern of a mother's weight gain during pregnancy affects the size and health of the baby.

3. I understand that my participation in this research project will be for a period of one visit today, and every time I bring my baby in for health visits (approximately 7 visits). I may participate today even if I know that I will not be able to participate in the future.

4. The procedures for this project include the following:

a. If I choose to participate in this study today, study staff will:

(1) weigh me on a scale in the clinic and measure my height;

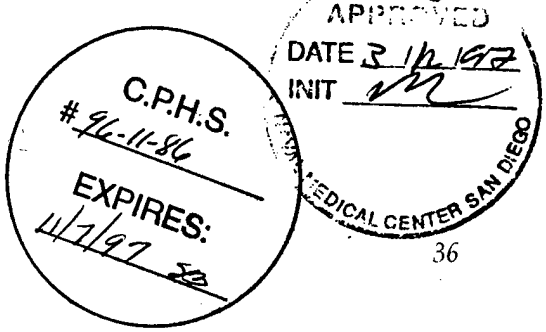
(2) ask me to complete a questionnaire providing information about my current lifestyle (for example, infant feeding, work, diet and exercise) and my views about diet and weight. Study staff estimate it will take about 20 minutes to complete this questionnaire. (If my baby is two weeks old at this visit, study staff will give me a shorter questionnaire (5-10 minutes) today and ask me to complete the longer one at my next visit);

Subject's Initials: _____ Date: _____

Witness's Initials: _____ Date: _____

CPH/IRB Approval stamp/Seal required

Revised March 3, 1997



(3) ask me to sign a form giving the study staff permission to examine my prenatal medical records, and if I am on active-duty, my Physical Readiness Test (PRT) records. Study staff will only examine and record information in my prenatal record that is directly related to this study (for example, military status, my weight gain in pregnancy, pregnancy complications and infant size). The PRT records will be examined for information on my weight and PRT test scores for the last test I took prior to becoming pregnant and for the first test I took or will take after the baby is born; and

(4) study staff will also request my social security number so that they can examine information on my baby's birth certificate. This will allow them to understand who participated in their study compared to all women who had babies in California delivered during the same year.

b. Once I enroll in this study, study staff will meet me every time I bring my baby in for a regularly scheduled well-care visits. Study staff will:

(1) weigh me on a scale in the clinic;

(2) ask me to complete a short questionnaire (approximately 5 - 10 minutes to fill out); and

(3) ask me to fill out a second 20 minute questionnaire at my baby's 12 month visit.

Even if I plan to move away or miss future visits, I may still participate today.

c. Study staff may recontact me to verify or clarify some of my answers on the questionnaires. My responses will be entered into a database which will be used to gain important knowledge about the health of mothers and their infants.

5. A total of 4000 subjects are expected to participate in this study from the Naval Medical Center, San Diego.

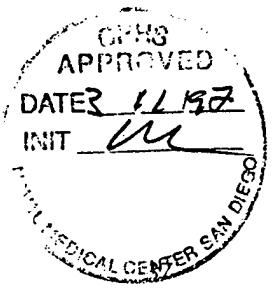
6. The risks or discomforts to me while participating in this study are very small. There is a possibility that some of the questions could disturb me. I have the right to

Subject's Initials: _____ Date: _____

Witness's Initials: _____ Date: _____

CPH/IRB Approval stamp/Seal required

Revised March 3, 1997



skip any questions which I do not wish to answer. My only other known discomfort from my participation in this study is the additional time it would take me to answer these questions and participate in this research study.

7. I understand that my participation in this research project may or may not be of direct benefit to me personally. However, the results of this study may help the investigator gain important knowledge about prenatal weight gain and infant health, and postpartum weight changes in new mothers that may benefit pregnant women and new mothers in the future.

8. I understand that researchers do not expect any of the information collected by this research project will be entered into my medical records about me. All data and medical information obtained about me as an individual will be considered privileged and held in confidence; I will not be identified in any presentation or publication of the results.

a. Research staff will take every precaution to preserve the confidentiality of the research information. All questionnaires will be stored in locked cabinets. Pre-assigned code numbers will be included in the body of each questionnaire as well as on a separate page on which identifying information is collected. After I complete the questionnaire and it is assessed by study staff for completeness, the page with subject identifiers and code number will be immediately detached from the coded questionnaire. Thus, questionnaire data will be entirely unidentifiable. Identifying information will be stored in a separate data file, and a linking number will be required to connect the identifying information with subject data.

b. Abstraction of records will be accomplished using a laptop computer by trained project staff who will sign a confidentiality agreement and examine only information specifically required by the study. After data from various sources merged, all identifying information will be purged, so that the final analytic data set contains no identifying information.

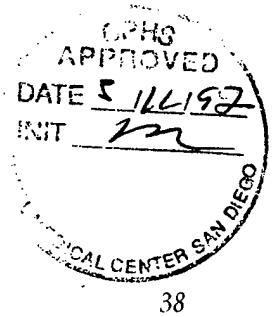
c. I also understand that complete confidentiality cannot be promised, particularly to subjects who are military personnel, because information bearing on my health may be required to be reported to appropriate medical or command authorities. It should be noted that representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as a part of their responsibility to protect human subjects in research.

Subject's Initials: _____ Date: _____

Witness's Initials: _____ Date: _____

CPH/IRB Approval stamp/Seal required

Revised March 3, 1997



9. If I suffer any injury directly related to my participation in this research study, immediate medical attention is available at the Naval Medical Center, San Diego, or at another closer military medical treatment facility, if applicable. I must be eligible for DoD medical care to be eligible for this study. I understand that although no financial compensation is available, any injury resulting from my participation in this study will be evaluated and treated in keeping with the benefits or care to which I am entitled under applicable Navy, other Department of Defense, and other state or Federal regulations.

10. If I have any questions regarding this research study, I may contact **Dr. Everett Magann**, Director, Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, NMCSD at **(619) 532-7004** or **Dr. Timothy Shope**, Department of Pediatrics, NMCSD at **(619) 532-6584**. I may also call (collect) **Professor Barbara Abrams**, Associate Professor, UC Berkeley at **(510) 642 4216**. If I have any questions about my rights as an individual while participating in a research study at the Naval Medical Center, San Diego, I may contact **CDR Dean Gubler**, MC, USN, Chairman, Committee for the Protection of Human Subjects at **(619) 532-8125** or **CAPT Charles Gray**, MC, USN, Department Head, Clinical Investigation Department at **(619) 532-8127**. If I believe that I have been injured as a result of my participation in this research study, I may contact **CDR K. Allred**, JAGC, USN, at the Naval Medical Center, San Diego, Legal Department at **(619) 532-6475**.

11. I understand that my participation in this project is entirely voluntary and that my decision not to participate will involve no penalty or loss of benefits to which I am entitled under applicable regulations. If I choose to participate, I am free to ask questions or to withdraw from the study at any time. If I should decide to withdraw from the research project, I will notify **Dr. Everett Magann** at **(619) 532-7004, Dr. Timothy Shope** at **(619) 532-6584** or **Professor Barbara Abrams** at **(510) 642-4216**. My withdrawal will involve no prejudice to my future health care or any loss of rights or benefits to which I am otherwise entitled. Any new significant finding developed during the course of this study which might affect my willingness to continue participation will be communicated to me.

12. The investigator may terminate my participation in this study at the investigator's discretion.

Subject's Initials: _____ Date: _____

Witness's Initials: _____ Date: _____

CPH/IRB Approval stamp/Seal required

Revised March 3, 1997

13. I have been informed that there will not be additional costs to me if I choose to participate in this project.

14. I understand that I am making a decision whether or not to participate in the research project described in the preceding sections subject to the conditions of participation described above. My signature indicates that I have decided to participate, having read and understood the information presented above and having been given the opportunity to ask any questions that I might have about the research study or my participation in the study. Further, my signature indicates that I have been provided with a copy of this consent document and a copy of a document entitled, "Experimental Subject's Bill of Rights".

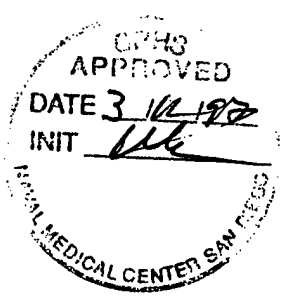
15. I have been informed that I will be provided a copy of the results of this study at my request.

SIGNATURES AND DATE SIGNED: PRINTED/TYPED IDENTIFICATION:

Patient / Subject	(Date)	Name / Status / Sponsor's SSN	
Witness	(Date)	Name / Grade or Rank / SSN	
Researcher/Investigator	(Date)	Name / Grade or Rank / SSN	

CPH/IRB Approval stamp/Seal required

Revised March 3, 1997



PRIVACY ACT STATEMENT

1. Authority. 5 USC 301

2. Purpose. Medical research information will be collected to enhance basic medical knowledge or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury, or functional impairment.

3. Use. Medical research information will be used for statistical analysis and reports by the Department of the Navy, the Department of Defense, and other U.S. Government agencies, provided this use is compatible with the purpose for which the information was collected. Use of the information may be granted to non-Government agencies or individuals by the Chief, Bureau of Medicine and Surgery in accordance with the provisions of the Freedom of Information Act.

4. Disclosure. I understand that all information contained in this Consent Statement or derived from the medical research study described herein will be retained permanently at Naval Medical Center San Diego and salient portions thereof may be entered into my health record. I voluntarily agree to its disclosure to agencies or individuals identified in the preceding paragraph. I have been informed that failure to agree to such disclosure may negate the purposes for which the research study was conducted.

SIGNATURES AND DATE SIGNED: **PRINTED OR TYPED IDENTIFICATION:**

Patient / Subject (Date) (if Applicable)	Name / Status / Sponsor's SSN
Parent / Guardian (Date) (if Applicable)	Name / Status / SSN
Witness (Date)	Name / Grade or Rank / SSN

IRB APPROVED DATE 5 MAY 96 INIT

NAVAL MEDICAL CENTER SAN DIEGO

CALIFORNIA EXPERIMENTAL SUBJECTS BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment;

2. Be given an explanation of the procedures to be followed in the medical experiment and any drug or device to be used;

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment;

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable;

5. Be given a disclosure of appropriate alternative procedures, drugs, or devices that might be advantageous to the subject and their relative risks and benefits;

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if any complications should arise;

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved;

8. Be instructed that the consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice;

9. Be given a copy of a signed and dated written consent form when one is required;

10. Be given the opportunity to decide to consent or not consent to medical experiment without intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision; and

11. Be assured that the subject's confidentiality will be preserved and his/her name will not be released without his/her permission.

Any questions regarding this research study should be directed to the principal investigator or associate investigators. Information is available from the Chairman, Committee for the Protection of Human Subjects, established for the protection of volunteers in research projects at this facility by calling (619) 532-8125 or writing the Chairman, Committee for the Protection of Human Subjects at Naval Medical Center, Clinical Investigation Department (Code AVA), San Diego, CA 92134-5000.

Appendix F: Daily Follow up Tally Sheet

DAILY FOLLOW-UP TALLY SHEET

DATE:			
SHIFT START:	SHIFT END:	TOTAL FOLLOW-UP HOURS:	PROJECT #: 628

FOLLOW-UP APPOINTMENTS

DISPOSITION CODES

1 (R) Refused
2 (L) Con. Later
3 (N) NS/Cancel
4 (M) Rec Missed Appt
8 (FC) Follow-up Complete
9 (FI) Follow-up Incomplete
11 No Longer Participating
12 Other Than Mother

	Pre-record FSCID # for Follow-up Visits From Appt. List		Record Weight for Follow-up Visit			
	FSCID # / Full SS# r W- Well-Baby A- Other		WEIGHT #1	Visit #	Recruiter Initials	Disposition Code
1		1				
2		2				
3		3				
4		4				
5		5				
6		6				
7		7				
8		8				
9		9				
10		10				
11		11				
12		12				
13		13				
14		14				
15		15				
TALLY TOTALS						

NOTES:

Appendix G: ABC Study Variables

Appendix G

Table of ABC Study Variables Captured by Data Collection Instrument

Subject	*Question*	*3-7 Days*	*10-16 Days*	*Baseline*	*2,4,6,9 & 12 Month*	*Follow-Up*	*MRA*
Timing	date of instrument completion			X		X	X
	which visit (2,4,6,9,12 month,other)				X		
Mom's Health	scale from excellent to poor (past 7 days)	X	X		X		
Lactation	type of milk baby fed	X	X		X		
	# times/night				X		
	longest amount of continuous sleep				X		
	# times baby woke mom up				X		
	other foodsbaby receiving				X		
	age of baby when first fed non-breast milk					X	
	age of baby when stopped breast feeding					X	
	reasons stopped breast feeding					X	
Baby's Health	any hospitalizations				X		
	any developmental specialists				X		
Menstruation	last period befor pregnancy						X
	when first had after the birth (date)				X		
	current pregnancy status				X		
	type of birth control using				X		
Physical Activity (current)	work status			X	X	X	
	# hours spend at work/school			X	X		
	days of heavy lifting/week			X	X		
	hours of heavy lifting/day				X		
	date returned to work/school			X		X	
	job title or rank			X		X	
	three most time consuming activities			X		X	
	amount sat, stood, walked, lifted, sweated, was tired			X		X	
	how compare job's activities to those of peers			X		X	
	sports or exercise/week		X	**Detail**	X	**Detail**	
	riding, walking/week		X	X	X	X	
	usual walking pace			X		X	
	vigorous household chores/week		X		X		
Barriers to Exercise	has anything interfered w/ability to exercise			X	X		
	reasons for inability to exercise			X	X		
Stress	amount feel in general	X	X		X		
	amount feel about child's care				X		
Depression	how much felt during past 7 days			**Detail**	X	**Detail**	
Worries (current)	weight	X	X		X		
	body shape	X	X		X		
	amount eat	X	X		X		

Subject	Question	3-7 Days	10-16 Days	Baseline	2,4,6,9 & 12 Month	Follow-Up	MRA
	appearance	X	X		X		
Spousal Relationship	does currently have a spouse		X		X		
	satisfaction with them		X		X		
	is spouse at home 5 nights/wk		X		X		
	was spouse deployed in past 7 days		X		X		
	how much helping with baby's care/household chores		X		X		
	how much providing emotional support		X		X		
Family & Friends	how much helping with baby's care/household chores		X		X		
	how much providing emotional support		X		X		
Financial	can pay bills this month	X	X		X		
PRT/PT (active duty women only)	level of concern about next PRT		X		X		
	anticipated result		X		X		
	when took last PRT			X		X	
	result			X		X	
	how much weight need to lose to be w/in standard				X		
	PT status of current assignment				X		
	how many days/wk				X		
	for how long				X		
Parity	# of other children			X			X
	# under 5yrs.			X			
Dieting Success	# times lost 10 lbs.			X			
	# times gained back			X			
PA (during preg, by trimester)	how often sports or exercise			X			
	how often ride, walk			X			
	how often at work/lifting heavy loads			X			
	how often around house			X			
Complications/ Conditions	diabetes before preg			X			
	insulin			X			
	diabetes during preg			X			
	insulin			X			
	hypertension/preeclampsia			X			
	which trimesters			X			
	C-section			X			
	was it the first			X			
	tubes tied			X			
Weight and Perception of It	weight before preg			X			X
	how felt about it			X			
	satisfaction with amount gained in pregnancy		X	X		X	
	amount gained		X	X		X	**Detail**
	amount advised to gain		X	X			
	were told to gain more			X			
	by whom			X			

Subject	Question	3-7 Days	10-16 Days	Baseline	2,4,6,9 & 12 Month	Follow-Up	MRA
	what did to gain more			X			
Weight and	were told to gain less			X			
Perception of It	by whom			X			
(Con't.)	what did to control weight			X			
	what doing now (past 7 days) to control weight				X		
	what did after birth to control weight					X	
	what worked best					X	
	what consider your ideal weight			X		X	
	how classify current weight			X	X		
Dietary	amount of food					X	
Comparisons	amount of fruit, vegetables & juices					X	
(during preg and	amount of milk					X	
2-3 mos after vs. now)	amount of junk/fast food					X	
Shape (pics.)	how look today			X	X		
	how would like to look			X		X	
	shape spouse wants you to have			X			
	biological mother's shape			X			
	heaviest time of biological mom			X			
	biological father's shape			X			
Family Weight	is biological mother currently overweight					X	
Status	is biological father currently overweight					X	
	are any biological sisters currently overweight					X	
	are any biological brothers currently overweight					X	
Mom's History	age at menstruation			X			
	how looked (shape)			X			
	shape at 18			X			
	weight perception as a child			X			
	ever had an eating disorder					X	
Substance Use	smoked >99 cigs. in life			X			
	any smoking during preg			X			
	amount (by trimesters)			X			
	any cigarettes during past 7 days			X		X	
	number per day			X		X	
	any alcohol since baby's birth			X		X	
	how many drinks per week			X		X	
	how many drinks per day (when drink)			X		X	
Mom's SES	racial/ethnic classification			X			X
	age (date of birth)						X
	monthly income			X			
	active duty status						X
	pay grade						X
	title						X

Subject	Question	3-7 Days	10-16 Days	Baseline	2,4,6,9 & 12 Month	Follow-Up	MRA
	WIC status during preg			X			
Mom's SES (con't.)	which trimesters			X			
	WIC status currently			X			
	marital status			X			X
	years of education			X			
Spouse/Partner	spouse/partner's military rank			X			
Deployment Detail	deployment status since the birth			X		X	
	when left			X		X	
	when to return			X		X	
Dad Info.	height			X			
	weight			X			
	race/ethnicity			X			
Measurements	baby's length	X	X		X		
	baby's weight	X	X		X		
	baby's head circumference	X	X		X		
	mom's height	X	X		X		
	mom's weight	X	X		X		
Medical Info.	method of delivery						X
	delivery date						X
	sex of child						X
	birthweight of child						X
	post-delivery hematocrit						X
	sonogram results						X

Appendix H: Selected Questionnaires

2,4,6,9 and 12 Month Clinic

Baseline Take-Home

The A^B C Study

"After the Baby Comes"

2, 4, 6, 9 and 12 Month Well-Baby Questionnaire for Moms

1. **Which type of visit are you here for today?**

☐3	☐4	☐5	☐6	☐7	☐8
2 month Well Baby	4 month Well Baby	6 month Well Baby	9 month Well Baby	12 month Well Baby	Other Type of Visit

2. **How would you describe your health during the past 7 days?**

☐1	☐2	☐3	☐4
Excellent	Good	Fair	Poor

3. **During the past 7 days, what kind of milk has your baby been fed?**
   - ☐1 Breast milk only *(This includes pumped breast milk in a bottle.)*
   - ☐2 Mostly breast milk and some infant formula/milk
   - ☐3 About half of both breast milk and infant formula/milk
   - ☐4 Mostly infant formula/milk and some breast milk
   - ☐5 Infant formula/milk only *(and no breast milk)* → *GO TO QUESTION 5*

4. **If you are breast feeding, during the past 7 days, on a typical night between 11:00PM and 7:00AM, how many times did you wake up to breast feed the baby?**

   _____ *times (if none, enter "0")*

5. **During the past 7 days, what was the longest amount of continuous sleep you had?** *(Include naps and sleep during the day as well as at night.)*

   _____ *hours*

6. **During the past 7 days, on a typical night, how many times did your baby wake you up, even if you didn't get out of bed?** *(This includes breast feeding times.)*

   _____ *times per night (if none, enter "0")*

7. **During the past 7 days, was your baby fed any of the following foods?** *(check all that apply)*

- ☐ a Cereals
- ☐ b Fruits or vegetables *(not including juices)*
- ☐ c Meats
- ☐ d None of the above

8. **Since your baby's last Well-Baby appointment, has s/he been hospitalized?**

- ☐ 1 Yes
- ☐ 2 No

9. **Since your baby's last Well-Baby appointment, has your baby been seen by a developmental specialist?**

- ☐ 1 Yes
- ☐ 2 No

10. **Have you had your menstrual period since your baby was born?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO, GO TO QUESTION 12*

11. **<u>If you have had your period</u>, what was the first day of your last menstrual period?**

_____ / _____ / _____
Month Day Year

12. **Are you currently pregnant?**

- ☐ 1 Yes → *IF YES, GO TO QUESTION 14*
- ☐ 2 No
- ☐ 8 Not Sure

13. **<u>If you are NOT pregnant,</u> which of the following types of birth control or contraceptives are you currently using:**

- ☐ 1 Oral contraceptives *(The Pill)* → 13a **What brand?** _____
  Check box if don't know brand ☐ 8
- ☐ 2 Depo-Provera shots
- ☐ 3 Norplant *(a rod that is inserted into your arm)*
- ☐ 4 Condoms, Diaphragm, Cervical Cap or any other barrier method
- ☐ 5 Something else
- ☐ 6 I'm not using birth control right now
- ☐ 7 Tubes tied or hysterectomy

14. **Please indicate your work status during the last work week:**

- ☐ 1 I worked at a job *(for pay or as a volunteer)*
- ☐ 2 I went to school
- ☐ 3 I was on maternity leave → *GO TO QUESTION 18*
- ☐ 4 I'm not employed right now → *GO TO QUESTION 18*
- ☐ 5 I'm on another type of leave/vacation → *GO TO QUESTION 18*

15. **How many HOURS did you work or spend at school during the past 7 days?**

_____ *hours*

16. **During the past 7 days, how many DAYS did you work at a job that required walking, carrying or lifting heavy loads?** (Active Duty Women: include physical training or "PT" *)*

_____ *days*

17. **During the past 7 days, how many HOURS PER DAY did your job require walking, carrying, lifting heavy loads** (Active Duty Women: include physical training or "PT" *)*

_____ *hours/day (if none, enter "0")*

18. **During the past 7 days, how many times did you participate in any sports or exercise?**

Number of times in 7 days = _____ *times (if none, enter "0")*

19. **During the past 7 days, other than participating in sports or exercise, how many times did you walk or ride a bicycle for least 15 minutes at a time** *(to do errands or get to places)*?

Number of times in 7 days = _____ *times (if none, enter "0")*

20. **During the past 7 days, how many times did you do vigorous household chores, like vacuuming, gardening or scrubbing floors, for at least 15 minutes at a time?**

Number of times in 7 days = _____ *times (if none, enter "0")*

21. **During the past 7 days, has anything interfered with your ability to exercise?**

❑$_1$ Yes
❑$_2$ No → *IF NO, GO TO QUESTION 23*

22. **<u>If yes,</u> please check all of the following that have interfered with your ability to exercise?**

❑$_a$ I was too tired
❑$_b$ I didn't have adequate child care
❑$_c$ It was too expensive
❑$_d$ I was injured or ill
❑$_e$ I don't enjoy exercising
❑$_f$ There's no place to go exercise
❑$_g$ The neighborhood isn't safe
❑$_h$ I didn't have enough time
❑$_i$ It's too soon after my baby was born
❑$_j$ Another reason: *Please explain below:*

_____

23. **During the past 7 days, how often have you felt depressed?**

❑$_1$	❑$_2$	❑$_3$	❑$_4$
Rarely or none of the time	Some of the time	More than half of the time, but not most of it	Most or all of the time

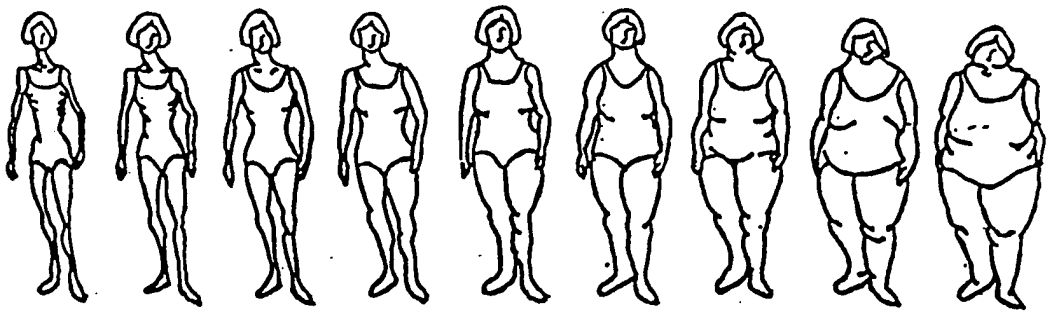
24. **During the past 7 days, which of the following things did you do to control or lose weight?** *(check all that apply)*

- ☐ a Ate less food
- ☐ b Followed a low calorie diet
- ☐ c Skipped meals
- ☐ d Fasted for at least one day
- ☐ e Participated in organized weight loss programs *(example: Weight Watchers, Jenny Craig ,etc)*
- ☐ f Participated in military-sponsored weight loss programs
- ☐ g Avoided junk foods *(examples: sweet or salty snacks, fast food, candy, etc.)*
- ☐ h Used herbal medications
- ☐ i Hypnosis, biofeedback, etc.
- ☐ j Relaxation, visualization, meditation, or stress reduction techniques
- ☐ k Psychotherapy or behavior modification
- ☐ l Received nutrition counseling from a dietitian or nutritionist
- ☐ m Received nutrition counseling from another health care provider
- ☐ n Smoked cigarettes
- ☐ o Meal replacements *(example: SlimFast)*
- ☐ p Took weight loss pills *(over-the-counter or prescription)*
- ☐ q Took laxatives to lose weight
- ☐ r Took diuretics or water pills
- ☐ s Intentionally vomited after eating
- ☐ t Used low calorie sweeteners *(examples: Equal, Sweet-N-Low, NutraSweet, etc.)*
- ☐ u Drank diet soft drinks
- ☐ v Bought low fat foods *(examples: low-fat salad dressing, low-fat ice-cream or low-fat cookies, etc)*
- ☐ w Liposuction
- ☐ x Tried to be more physically active
- ☐ y I worried but did nothing
- ☐ z Did nothing

25. **Currently, do you think you are ...**

☐ 1	☐ 2	☐ 3	☐ 4
Underweight	Just about the right weight	A little overweight	Very overweight

26. **Today, you look most like:**



❑1	❑2	❑3	❑4	❑5	❑6	❑7	❑8	❑9
A	B	C	D	E	F	G	H	I

27. **During the past 7 days, how often did you worry about your weight?**

❑1	❑2	❑3	❑4
Rarely or none of the time	Some of the time	More than half of the time, but not most of it	Most or all of the time

28. **During the past 7 days, how often did you worry about your body shape?**

❑1	❑2	❑3	❑4
Rarely or none of the time	Some of the time	More than half of the time, but not most of it	Most or all of the time

29. **During the past 7 days, how often were you concerned about how much you ate to lose or control your weight?**

❑1	❑2	❑3	❑4
Rarely or none of the time	Some of the time	More than half of the time, but not most of it	Most or all of the time

30. **During the past 7 days, how often did you worry about your appearance?**

❑1	❑2	❑3	❑4
Rarely or none of the time	Some of the time	More than half of the time, but not most of it	Most or all of the time

31. **Having a baby adds a lot of responsibilities to the lives of mothers. During the past 7 days, how often have you felt stressed?**

❑ 1	❑ 2	❑ 3	❑ 4
Rarely or none of the time	Some of the time	More than half of the time, but not most of it	Most or all of the time

32. **During the past 7 days, how often have you felt stress or concern about child care for your baby?**

❑ 1	❑ 2	❑ 3	❑ 4
Rarely or none of the time	Some of the time	More than half of the time, but not most of it	Most or all of the time

33. **Do you currently have a spouse or partner?**

❑ 1 Yes
❑ 2 No → *IF NO, GO TO QUESTION **41, page 8***

34. **How satisfied are you with your relationship with your spouse/partner?**

❑ 1	❑ 2	❑ 3	❑ 4
Very satisfied	Satisfied	Dissatisfied	Very dissatisfied

35. **Is your spouse or partner <u>currently</u> living with you at least 5 nights a week?**

❑ 1 Yes → *IF YES, GO TO QUESTION 37*
❑ 2 No

36. **<u>If no,</u> has your spouse or partner been deployed during the past 7 days?**

❑ 1 Yes → *IF YES, GO TO QUESTION 39*
❑ 2 No

37. **Are you getting help at home with taking care of your baby and household chores from your spouse or partner?**

❑ 1 Yes
❑ 2 No → *IF NO, GO TO QUESTION 39*

38. **<u>If yes</u>, do you feel that you are getting** *(from spouse or partner)*

❑ 1	❑ 2	❑ 3
As much help as you need	Some help , but not enough	Just a little help

39. **Are you getting <u>emotional support</u> as a mother of a new baby from your spouse or partner?**

❑ 1 Yes
❑ 2 No → *IF NO, GO TO QUESTION 41*

40. **<u>If yes</u>, do you feel that you are getting** *(from spouse or partner)*

❑ 1	❑ 2	❑ 3
As much support as you need	Some support, but not enough	Just a little support

41. **Are you getting help at home with taking care of your baby and household chores from your family, friends or from paid help?**

❑ 1 Yes
❑ 2 No → *IF NO, GO TO QUESTION 43*

42. **<u>If yes</u>, do you feel that you are getting** *(from your family, friends or from paid help)*

❑ 1	❑ 2	❑ 3
As much help as you need	Some help , but not enough	Just a little help

43. **Are you getting <u>emotional support</u> as a mother of a new baby from your family and friends?**

❑ 1 Yes
❑ 2 No → *IF NO, GO TO QUESTION 45*

44. **<u>If yes</u>, do you feel that you are getting** *(from your family, friends or from paid help)*

❑ 1	❑ 2	❑ 3
As much support as you need	Some support, but not enough	Just a little support

45. **Do you have enough money to pay your bills this month?**

- ☐ 1 Yes
- ☐ 2 No
- ☐ 8 Not Sure
- ☐ 9 Decline

The following questions are for ACTIVE DUTY WOMEN only.
If you are not active duty, please STOP here.
Thank You!

46. **How concerned are you about taking your next physical readiness test?**

- ☐ 1 Not at all concerned
- ☐ 2 Somewhat concerned
- ☐ 3 Very concerned
- ☐ 4 Extremely concerned

47. **What do you think the results of your next physical readiness test will be?**

- ☐ 1 I expect to pass
- ☐ 2 I will probably pass
- ☐ 3 I'm not sure if I'll pass
- ☐ 4 I don't expect to pass
- ☐ 5 I'm not sure how I'll do

48. **How much weight do you need to lose to be within your weight standard?**

_____ ***pounds*** *(if none, enter "0")*

☐ 888 Not Sure

49. **Does your <u>current</u> duty assignment have Physical Training** *(PT)*?

- ☐ 1 Yes
- ☐ 2 No → ***STOP. Thank you!***

50. **Is the Physical Training *(PT)* for your <u>current</u> duty assignment mandatory or voluntary?**

- ☐ 1 Mandatory
- ☐ 2 Voluntary

51. **Is PT done ....**

- ☐ 1 As part of a group
- ☐ 2 Individually
- ☐ 3 Both

52. **For your <u>current</u> duty assignment, is time allotted during the workday for PT?**

- ☐ 1 Yes
- ☐ 2 No → ***STOP. Thank you!***

53. **How many days per week are you expected to do PT?**

_____ ***days*** *(if none, enter "0")*

54. **How long are you expected to do PT each time you do it?**

_____ ***minutes*** *(if none, enter "0")*

ACTIVE DUTY WOMEN STOP HERE. - Thank you!

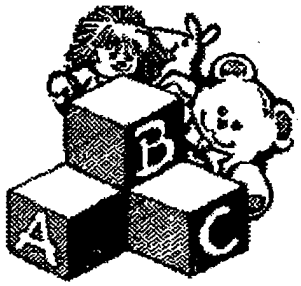
Official personnel complete this part: **Initials** ___ ___ ___

Baby's Length (cms)	Baby's Weight (kgs)	Baby's Head Circumference (cms)
___ ___ ___	___ . ___ ___	___ ___ ___
Mother's Ht. (cms)	**Mother's Weight (kgs)**	**Today's Date (mo/day/yr)**
① ___ ___ ___ . ___	① ___ ___ ___ . ___	___ ___ /___ ___ /___ ___
② ___ ___ ___ . ___	② ___ ___ ___ . ___	
③ ___ ___ ___ . ___	③ ___ ___ ___ . ___	
If ① & ② are the same STOP. If height ① & ② differ by more than ± 5mm, do height ③	If ① & ② are the same STOP. If weight ① &② differ by more than ± 0.1 kg, do weight ③	

Official Use Only: FSCID 628 ___ ___ ___ ___ ___

The A B C Study

"After the Baby Comes"



Take-Home Questionnaire for Moms

Thank you for taking the time to complete this questionnaire

- The information on this page is for tracking purposes only
- To protect your privacy, the lower half of this page will be separated from the questionnaire before processing
- Please complete the following:

Your baby's sponsor's SSN: ___ ___ ___- ___ ___- ___ ___ ___ ___	
Your baby's first name:	**Baby's date of birth:** ___/___/___
Your name:	

- Answer all the questions on the following pages as instructed
- There are no right or wrong answers - we are interested in how you and your baby are doing
- **Please complete this questionnaire in the next few days and return it to our San Francisco office using the enclosed postage-paid envelope**
- You will be mailed a check for **$10** approximately two weeks after we receive your completed questionnaire

Thank you! - Continue to next page ⇨

1. **Today's date:** ____ / ____ / ____

2. **Not including your new baby, how many <u>other</u> children do you have?** (*Include biological, adopted, foster and step children who live with you at least 5 days a week.*)

   Number of children = _____ *(if none, enter "0" and GO TO QUESTION 4)*

3. **How many of these other children under the age of 5?**

   Number of children under 5 years old = _____ *(if none, enter "0")*

4. **How many times in your life have you lost at least 10 pounds as a result of dieting and/or exercise?** *(This should only be weight loss not related to a pregnancy.)*

   ❑1 Once ❑2 twice ❑3 3 times ❑4 4 times ❑5 5-10 times ❑6 10-20 times ❑7 21 or more

   ❑8 Never → *IF NEVER, GO TO QUESTION 6*

5. **How many times in your life have you gained <u>all</u> of the weight back?** *(Do not include weight gained during pregnancy)*

   ❑1 Once ❑2 twice ❑3 3 times ❑4 4 times ❑5 5-10 times ❑6 10-20 times ❑7 21 or more

   ❑8 Never

6. **<u>ACTIVE DUTY WOMEN ONLY:</u> When was the last time you took a Physical Readiness Test?**
   (Please give the month and year in the space provided.)

   _____ / _____
   Month *Year*

7. **<u>ACTIVE DUTY WOMEN ONLY:</u> What was the result of your last Physical Readiness Test?**

   ❑1 Fail ❑2 Good ❑3 Excellent ❑4 Outstanding

For the following questions, think back to when you were pregnant with your new baby

8. **During the <u>first trimester</u>** *(0-12 weeks)*, **how often did you participate in any sports or exercise?**

❑1	❑2	❑3	❑4	❑5
never or less than once a month	1 - 3 times a <u>month</u>	once a week	2 - 3 times a <u>week</u>	more than 3 times a week

9. **During the <u>first trimester</u>** *(0-12 weeks)*, **other than participating in sports or exercise, how many times did you walk or ride a bicycle for least 15 minutes at a time** *(to do errands or get to places)*?

❑1	❑2	❑3	❑4	❑5
never or less than once a month	1 - 3 times a <u>month</u>	once a week	2 - 3 times a <u>week</u>	more than 3 times a week

10. **During the <u>first trimester</u>** *(0-12 weeks)*, **how often did you work at a job that required walking or carrying or lifting heavy loads more than half the time?**

❑1	❑2	❑3	❑4	❑5
never or less than once a month	1 - 3 times a <u>month</u>	once a week	2 - 3 times a <u>week</u>	more than 3 times a week

11. **During the <u>first trimester</u>** *(0-12 weeks)*, **how often did you do vigorous household chores, like vacuuming, gardening or scrubbing floors, for at least 15 minutes at a time?**

❑1	❑2	❑3	❑4	❑5
Never or less than once a month	1 - 3 times a <u>month</u>	once a week	2 - 3 times a <u>week</u>	more than 3 times a week

12. **During the <u>second trimester</u>** *(13-28 weeks)*, **how often did you participate in any sports or exercise?**

❑1	❑2	❑3	❑4	❑5
Never or less than once a month	1 - 3 times a <u>month</u>	Once a week	2 - 3 times a <u>week</u>	More than 3 times a week

13. **During the second trimester** *(13-28 weeks)*, **other than participating in sports or exercise, how many times did you walk or ride a bicycle for least 15 minutes at a time** *(to do errands or get to places)*?

❑1	❑2	❑3	❑4	❑5
Never or less than once a month	1 - 3 times a month	Once a week	2 - 3 times a week	more than 3 times a week

14. **During the second trimester** *(13-28 weeks)*, **how often did you work at a job that required walking or carrying or lifting heavy loads more than half the time?**

❑1	❑2	❑3	❑4	❑5
Never or less than once a month	1 - 3 times a month	Once a week	2 - 3 times a week	more than 3 times a week

15. **During the second trimester** *(13-28 weeks)*, **how often did you do vigorous household chores, like vacuuming, gardening or scrubbing floors, for at least 15 minutes at a time?**

❑1	❑2	❑3	❑4	❑5
never or less than once a month	1 - 3 times a month	Once a week	2 - 3 times a week	more than 3 times a week

16. **During the third trimester** *(29 weeks - delivery)*, **how often did you participate in any sports or exercise?**

❑1	❑2	❑3	❑4	❑5
never or less than once a month	1 - 3 times a month	once a week	2 - 3 times a week	more than 3 times a week

17. **During the third trimester** *(29 weeks - delivery)*, **other than participating in sports or exercise, how many times did you walk or ride a bicycle for least 15 minutes at a time** *(to do errands or get to places)*?

❑1	❑2	❑3	❑4	❑5
never or less than once a month	1 - 3 times a month	once a week	2 - 3 times a week	more than 3 times a week

18. **During the third trimester** *(29 weeks - delivery)*, **how often did you work at a job that required walking or carrying or lifting heavy loads more than half the time?**

❑1	❑2	❑3	❑4	❑5
never or less than once a month	1 - 3 times a month	once a week	2 - 3 times a week	more than 3 times a week

19. **During the <u>third trimester</u>** *(29 weeks - delivery),* **how often did you do vigorous household chores, like vacuuming, gardening or scrubbing floors, for at least 15 minutes at a time?**

❑1	❑2	❑3	❑4	❑5
never or less than once a month	1 - 3 times a <u>month</u>	Once a week	2 - 3 times a <u>week</u>	more than 3 times a week

For the following questions, think about the past 7 days:

20. **Please indicate your work status during the past 7 days:**

- ❑1 I worked at a job *(for pay or as a volunteer)*
- ❑2 I went to school
- ❑3 I was on maternity leave ➔ *GO TO QUESTION 34, page 7*
- ❑4 I'm not employed right now ➔ *GO TO QUESTION 34, page 7*
- ❑5 I'm on another type of leave/vacation ➔ *GO TO QUESTION 34, page 7*

21. **How many hours did you work or spend at school during the past 7 days?**

_____ ***hours***

22. **During the past 7 days, how many DAYS did you work at a job that required walking or carrying or lifting heavy loads or Physical Training** *(PT – for active duty women)***?**

_____ ***days***

23. **On what date did you return to work or school?** _____ / _____ / _____
Month *Day* *Year*

24. **What is your job title/rate?**

_____

25. **Please list the three activities that you spend the most time doing at your job or school?**

a) _____

b) _____

c) _____

	Never	Seldom	Sometimes	Often	Always
26. In the past 7 days, at work I sat	❑1	❑2	❑3	❑4	❑5
27. In the past 7 days, at work I stood	❑1	❑2	❑3	❑4	❑5
28. In the past 7 days, at work I walked	❑1	❑2	❑3	❑4	❑5
29. In the past 7 days, at work I lifted heavy loads	❑1	❑2	❑3	❑4	❑5
30. In the past 7 days, at work I sweated from exertion	❑1	❑2	❑3	❑4	❑5
31. In the past 7 days, at the end of a day I was physically tired	❑1	❑2	❑3	❑4	❑5
32. In the past 7 days, at work I did Physical Training *(PT for active duty)*	❑1	❑2	❑3	❑4	❑5

33. Compared to women my own age, I think my job's activities are <u>physically</u>...

❑1	❑2	❑3	❑4	❑5
much heavier	heavier	as heavy	lighter	much lighter

34. **Please check all of the physical activities you have participated in during the past 7 days. Also indicate how many times you did these activities and the amount of time you spent doing them.**

	Activity	Check here if you did this	Check here if done as part of Active Duty Physical Training	Number of times you did this activity during the past 7 days?	On **average**, how long do you spend doing this activity **each time you do it?**
35.	Riding a bicycle for exercise	❑a	❑b	___ times	_____ hours _____ min.
36.	Swimming	❑a	❑b	___ times	_____ hours _____ min.
37.	Walking while pushing the baby in a stroller or carrying the baby in a front or back pack	❑a	❑b	___ times	_____ hours _____ min.
38.	Walking without the baby for exercise	❑a	❑b	___ times	_____ hours _____ min.
39.	Jogging or running	❑a	❑b	___ times	_____ hours _____ min.
40.	Aerobic exercise classes *(step, jazzercize, etc.)*	❑a	❑b	___ times	_____ hours _____ min.
41.	Postpartum or "baby and me" type classes	❑a	❑b	___ times	_____ hours _____ min.
42.	Yoga or stretching	❑a	❑b	___ times	_____ hours _____ min.
43.	Weight or muscle strengthening or calisthenics	❑a	❑b	___ times	_____ hours _____ min.
44.	Lifting weights	❑a	❑b	___ times	_____ hours _____ min.
45.	Exercise tapes or videos	❑a	❑b	___ times	_____ hours _____ min.
46.	Gardening	❑a	❑b	___ times	_____ hours _____ min.
47.	Using aerobic exercise equipment *(such as stairmaster, rowing machines, Nordic track, etc.)*	❑a	❑b	___ times	_____ hours _____ min.
48.	Another activity *(Please explain)* _____	❑a	❑b	___ times	_____ hours _____ min.

49. **During the past 7 days, has anything interfered with your ability to exercise?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO, GO TO QUESTION 51*

50. **<u>If yes,</u> please check all of the following that have interfered with your ability to exercise?**

- ☐ a I was too tired
- ☐ b I didn't have adequate child care
- ☐ c It was too expensive
- ☐ d I was injured or ill
- ☐ e I don't enjoy exercising
- ☐ f There's no place to go exercise
- ☐ g The neighborhood isn't safe
- ☐ h I didn't have enough time
- ☐ i It's too soon after my baby was born
- ☐ j Another reason: *Please explain below*

_____

51. **How many minutes do you walk and/or ride a bicycle per day to and from work, school and shopping?** *(Do not include any time reported in #34).*

- ☐ 1 Less than 5 minutes
- ☐ 2 5 to 15 minutes
- ☐ 3 15 to 30 minutes
- ☐ 4 30 to 45 minutes
- ☐ 5 More than 45 minutes

52. **What is your usual pace when you walk?**

- ☐ 1 Casual strolling – *(slower than 2 miles per hour or fewer than walking 4 city blocks in ten minutes)*
- ☐ 2 Neither fast nor slow *(about 2-3 miles per hour or 4-6 city blocks in ten minutes)*
- ☐ 3 Fairly brisk - faster *(about 3-4 miles per hour or 6-8 city blocks in ten minutes)*
- ☐ 4 Very brisk - very fast *(more than 4 miles per hour or more than 8 city blocks in ten minutes)*

For the following questions, think about how you felt during the past 7 days:

		Rarely or none of the time	Some or a little of the time	More than half of the time, but not most of it	Most or all of the time
53.	During the past 7 days, I was bothered by things that don't usually bother me.	❑ 1	❑ 2	❑ 3	❑ 4
54.	During the past 7 days, I did not feel like eating; my appetite was poor.	❑ 1	❑ 2	❑ 3	❑ 4
55.	During the past 7 days, I felt I could not shake off the blues even with help from my friends.	❑ 1	❑ 2	❑ 3	❑ 4
56.	During the past 7 days, I felt that I was just as good as other people.	❑ 1	❑ 2	❑ 3	❑ 4
57.	During the past 7 days, I had trouble keeping my mind on what I was doing.	❑ 1	❑ 2	❑ 3	❑ 4
58.	During the past 7 days, I felt depressed.	❑ 1	❑ 2	❑ 3	❑ 4
59.	During the past 7 days, I felt that everything I did was an effort.	❑ 1	❑ 2	❑ 3	❑ 4
60.	During the past 7 days, I felt hopeful about the future.	❑ 1	❑ 2	❑ 3	❑ 4
61.	During the past 7 days, I thought my life had been a failure.	❑ 1	❑ 2	❑ 3	❑ 4
62.	During the past 7 days, I felt fearful.	❑ 1	❑ 2	❑ 3	❑ 4
63.	During the past 7 days, my sleep was restless.	❑ 1	❑ 2	❑ 3	❑ 4
64.	During the past 7 days, I was happy.	❑ 1	❑ 2	❑ 3	❑ 4
65.	During the past 7 days, I talked less than usual.	❑ 1	❑ 2	❑ 3	❑ 4

		Rarely or none of the time	Some or a little of the time	More than half of the time, but not most of it	Most or all of the time
66.	During the past 7 days, I felt lonely.	❑ 1	❑ 2	❑ 3	❑ 4
67.	During the past 7 days, people were unfriendly.	❑ 1	❑ 2	❑ 3	❑ 4
68.	During the past 7 days, I enjoyed life.	❑ 1	❑ 2	❑ 3	❑ 4
69.	During the past 7 days, I had crying spells.	❑ 1	❑ 2	❑ 3	❑ 4
70.	During the past 7 days, I felt sad.	❑ 1	❑ 2	❑ 3	❑ 4
71.	During the past 7 days, I felt that people disliked me.	❑ 1	❑ 2	❑ 3	❑ 4
72.	During the past 7 days, I could not get going.	❑ 1	❑ 2	❑ 3	❑ 4

For the following questions, think back to when you were pregnant with your new baby:

73. **<u>Before</u> you were pregnant, did you have diabetes?**

❑ 1 Yes
❑ 2 No ➔ *IF NO, GO TO QUESTION 75*

74. **Did you take insulin for it?**

❑ 1 Yes
❑ 2 No

75. **Did you have diabetes at any time during your pregnancy?**

❑ 1 Yes
❑ 2 No ➔ *IF NO, GO TO QUESTION 77*

76. **Did you take insulin for it?**

- ☐ 1 Yes
- ☐ 2 No

77. **When you were pregnant, did a health care provider** *(doctor, nurse, midwife, etc.)* **tell you that you had hypertension, high blood pressure or pre-eclampsia?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO, GO TO QUESTION 79*

78. **During which part of your pregnancy did you have this condition?**

- ☐ 1 During the first half *(1-20 weeks)*
- ☐ 2 During the second half *(21 weeks - delivery)*
- ☐ 3 During the entire pregnancy

79. **Was this baby born by cesarean section (c-section)?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO, GO TO QUESTION 81*

80. **<u>If yes,</u> was this your first cesarean delivery?**

- ☐ 1 Yes
- ☐ 2 No

81. **Did you get your tubes tied after giving birth to this baby?**

- ☐ 1 Yes
- ☐ 2 No

82. **What was your weight before you got pregnant with this baby?**

_____ ***pounds***

83. **<u>At that weight</u>, did you think you were...**

❑ 1	❑ 2	❑ 3	❑ 4
Underweight	just about the right weight	a little overweight	very overweight

84. **It's both natural and expected to gain weight during pregnancy. How satisfied are you with the amount of weight that you gained when you were pregnant?**

❑ 1	❑ 2	❑ 3	❑ 4
Very satisfied	Satisfied	Dissatisfied	Very dissatisfied

85. **How much weight did you gain during your pregnancy?**

____ ***pounds***

86. **How much weight were you advised to gain by your health care provider** *(either your doctor, nurse, physician's assistant or midwife)***?**

____ ***pounds*** ❑ 99 not advised ❑ 88 not sure

87. **During your pregnancy, did anyone tell you that you were <u>not</u> gaining enough weight?**

❑ 1 Yes

❑ 2 No ➔ *IF NO, GO TO QUESTION **90***

88. **<u>If yes</u>, who told you this?** *(please check all that apply)*

❑ a spouse or partner	❑ f midwife
❑ b friend	❑ g nurse/nurse practitioner
❑ c mother	❑ h nutritionist or dietitian
❑ d other family member	❑ i WIC staff
❑ e doctor	❑ j commanding officer

89. **Which of the following things did you do to try to gain more weight during your pregnancy?** *(please check all that apply)*

- ☐ a Worried but did nothing
- ☐ b Got nutrition counseling from a dietitian or nutritionist
- ☐ c Got nutrition counseling from another health care provider
- ☐ d Quit smoking cigarettes
- ☐ e Ate more food at meals
- ☐ f Added more meals or snacks
- ☐ g Ate higher calorie foods
- ☐ h Got more rest
- ☐ i Ate more junk foods
- ☐ j Ate healthier foods
- ☐ k Used meal supplements *(such as Instant Breakfast, Boost or Ensure)*
- ☐ l Stopped dieting
- ☐ m Exercised less
- ☐ n Other, *Please explain below:* _____
- ☐ o Nothing

90. **During your pregnancy, did anyone tell you that you were gaining too much weight?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO, GO TO QUESTION 92*

91. **If yes, who told you this?** *(please check all that apply)*

- ☐ a spouse or partner
- ☐ b friend
- ☐ c mother
- ☐ d other family member
- ☐ e doctor
- ☐ f midwife
- ☐ g nurse/nurse practitioner
- ☐ h nutritionist or dietitian
- ☐ i WIC staff
- ☐ j commanding officer

92. **Which of the following things did you do to control your weight during pregnancy?** *(check all that apply)*

- ☐ a Ate less food
- ☐ b Followed a low calorie diet
- ☐ c Skipped meals
- ☐ d Fasted for at least one day
- ☐ e Participated in organized weight loss programs *(example: Weight Watchers, Jenny Craig ,etc.)*
- ☐ f Participated in military-sponsored weight loss programs
- ☐ g Avoided junk foods *(examples: sweet or salty snacks, fast food, candy, etc.)*
- ☐ h Used herbal medications
- ☐ i Hypnosis, biofeedback, etc.
- ☐ j Relaxation, visualization, meditation, or stress reduction techniques
- ☐ k Psychotherapy or behavior modification
- ☐ l Received nutrition counseling from a dietitian or nutritionist
- ☐ m Received nutrition counseling from another health care provider
- ☐ n Smoked cigarettes
- ☐ o Meal replacements *(example: SlimFast)*
- ☐ p Took weight loss pills *(over-the-counter or prescription)*
- ☐ q Took laxatives to lose weight
- ☐ r Took diuretics or water pills
- ☐ s Intentionally vomited after eating
- ☐ t Used low calorie sweeteners*(examples: Equal, Sweet-N-Low, NutraSweet, etc.)*
- ☐ u Drank diet soft drinks
- ☐ v Bought low fat foods *(examples: low-fat salad dressing, low-fat ice-cream or low-fat cookies, etc.)*
- ☐ w Liposuction
- ☐ x Tried to be more physically active
- ☐ y I worried but did nothing
- ☐ z Did nothing

The following questions are about how you are today

93. **In your opinion, how much would you like to weigh?**

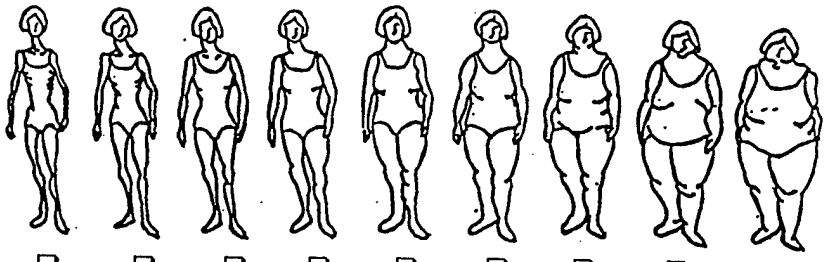
_____ ***pounds***

94. **Currently, do you think you are...**

☐ 1	☐ 2	☐ 3	☐ 4
Underweight	just about the right weight	a little overweight	very overweight

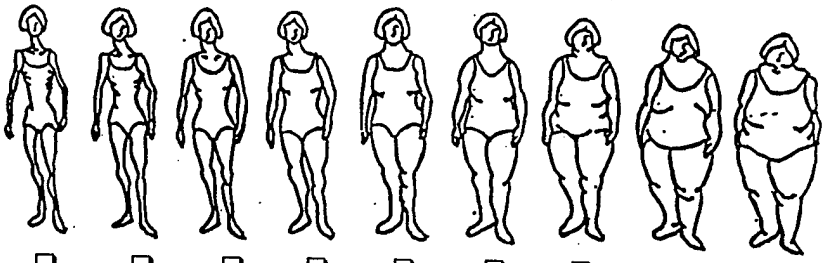
Below are some pictures of women of various sizes. Select the letter of the picture that comes closest to your response.

95. **Today, you look most like:**



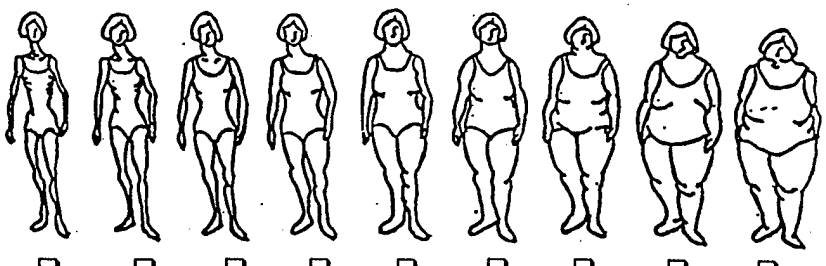
☐1 A ☐2 B ☐3 C ☐4 D ☐5 E ☐6 F ☐7 G ☐8 H ☐9 I

96. **You would like it best if you looked like:**



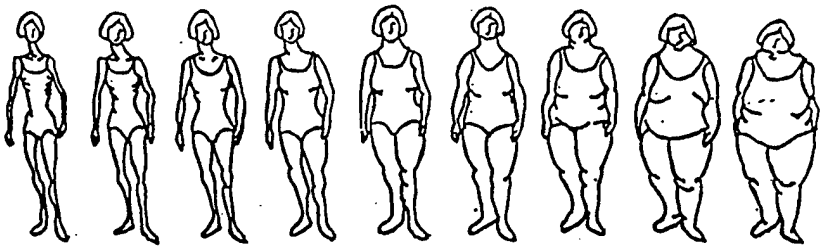
☐1 A ☐2 B ☐3 C ☐4 D ☐5 E ☐6 F ☐7 G ☐8 H ☐9 I

97. **Your spouse/partner wishes you looked like:** ☐88 DON'T KNOW ☐99 NOT APPLICABLE



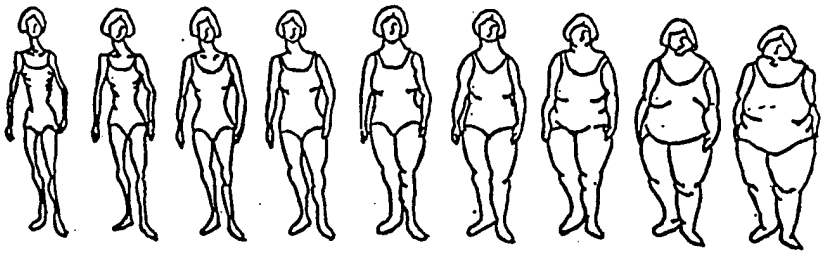
☐1 A ☐2 B ☐3 C ☐4 D ☐5 E ☐6 F ☐7 G ☐8 H ☐9 I

98. **Your biological mother usually looks(looked) like:** ☐ 88 DON'T KNOW
☐ 99 NOT APPLICABLE



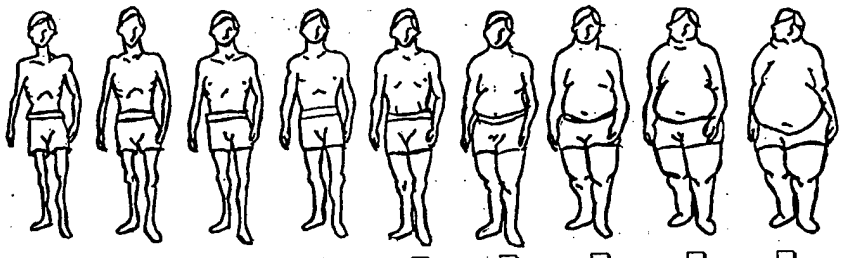
☐1 A ☐2 B ☐3 C ☐4 D ☐5 E ☐6 F ☐7 G ☐8 H ☐9 I

99. **When your biological mother was her <u>heaviest</u>** *(not including when she was pregnant)*, **she looked like:** ☐ 88 DON'T KNOW
☐ 99 NOT APPLICABLE



☐1 A ☐2 B ☐3 C ☐4 D ☐5 E ☐6 F ☐7 G ☐8 H ☐9 I

100. **Your biological father usually looks(looked) like:** ☐ 88 DON'T KNOW
☐ 99 NOT APPLICABLE



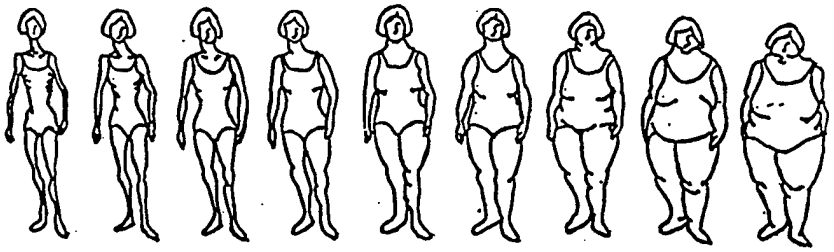
☐1 A ☐2 B ☐3 C ☐4 D ☐5 E ☐6 F ☐7 G ☐8 H ☐9 I

For the following questions, think about when you were younger and a child

101. **How old were you when you had your first menstrual period?** ☐ 88 DON'T KNOW

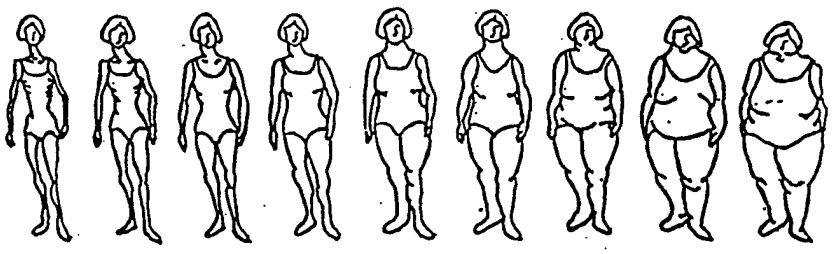
_____ *age of first period*

102. **When you had your first menstrual period, you looked most like:**



☐1 A ☐2 B ☐3 C ☐4 D ☐5 E ☐6 F ☐7 G ☐8 H ☐9 I

103. **When you were 18 years old, you looked most like** ☐ 88 DON'T REMEMBER ☐ 99 NOT 18 YET



☐1 A ☐2 B ☐3 C ☐4 D ☐5 E ☐6 F ☐7 G ☐8 H ☐9 I

104. **Overall, when you were a little girl, were you...**

☐ 1 Underweight ☐ 2 Just about the right weight ☐ 3 A little overweight ☐ 4 Very overweight

105. **Have you smoked at least 100 cigarettes (about 5 packs) in your lifetime?**

❑$_1$ Yes

❑$_2$ No → *IF NO, GO TO QUESTION 112*

106. **Did you smoke any cigarettes while you were pregnant with this baby?**

❑$_1$ Yes

❑$_2$ No → *IF NO, GO TO QUESTION 110*

107. **During the <u>first trimester</u>** *(0-12 weeks),* **on average, how many cigarettes did you smoke a day?**

First trimester = _____ ***cigarettes/day*** *(if none, enter "0")*

108. **During the <u>second trimester</u>** *(13-28 weeks),* **on average, how many cigarettes did you smoke a day?**

Second trimester = _____ ***cigarettes/day*** *(if none, enter "0")*

109. **During the <u>third trimester</u>** *(29 weeks - delivery),* **on average, how many cigarettes did you smoke a day?**

Third trimester = _____ ***cigarettes/day*** *(if none, enter "0")*

110. **During the past 30 days, did you smoke any cigarettes?**

❑$_1$ Yes

❑$_2$ No → *IF NO, GO TO QUESTION 112*

111. **On average, how many cigarettes did you smoke a day?**

_____ ***cigarettes/day***

112. **Since your baby's birth, have you drank any alcoholic beverages?** *(An alcoholic beverage includes beer, wine, wine coolers, mixed drinks or hard liquor.)*

❑$_1$ Yes

❑$_2$ No → *IF NO, GO TO QUESTION 115*

113. **During the past 7 days, how many days did you drink any alcoholic beverages?**

_____ ***days/week*** *(if none, enter "0")*

114. **On the days that you drank alcohol, on average how many drinks did you have?** *(One drink is either: a 12 ounce can of beer, a 6 ounce glass of wine, a 12 ounce wine cooler, or an ounce (one shot) of hard liquor, that may or may not be in a mixed drink.)*

_____ ***drinks/day***

115. **Would you describe yourself as....***(check all that apply)*

- ☐ a White
- ☐ b Black/African-American
- ☐ c Hispanic
- ☐ d Latina
- ☐ e Mexican
- ☐ f Cuban
- ☐ g Chinese
- ☐ h Japanese
- ☐ i Filipino
- ☐ k Another Asian ethnicity _____
- ☐ l Native American/Alaskan Native
- ☐ m Another group not listed _____

116. **What is the current monthly income, before taxes, for your household? Please include all sources for all family members. Include jobs, social security, retirement income, unemployment payments, WIC** *(Women, Infants and Children)* **etc.**

- ☐ 1 $500/month or less
- ☐ 2 $501 - $1000 / month
- ☐ 3 $1001 - $1500
- ☐ 4 $1501 - $2000
- ☐ 5 $2001 - $2500
- ☐ 6 $2501 - $3000
- ☐ 7 $3001 - $6250
- ☐ 8 More than $6250/month

117. **Were you on WIC when you were pregnant?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO, GO TO QUESTION 119*

118. **During which trimesters did you use it?**

- ☐ 1 First trimester *(0-12 weeks)*
- ☐ 2 Second trimester *(13-28 weeks)*
- ☐ 3 Third trimester *(29 weeks – delivery)*

119. **Are you currently receiving WIC for....** *(check all that apply)*

- ☐ 1 Your baby
- ☐ 2 Yourself

120. **What is your current marital status?**

- ☐ 1 Single, never married
- ☐ 2 Married
- ☐ 3 Separated or divorced
- ☐ 4 Widowed

121. **<u>If your spouse or partner is in the military,</u> what is his rank?**

_____

☐ 9 NOT APPLICABLE → GO ***TO QUESTION 125***

122. **Since your baby was born, has your spouse or partner been on deployment to another location?**

- ☐ 1 Yes
- ☐ 2 No → *IF NO GO TO QUESTION 125*

123. **<u>If your spouse or partner has been deployed,</u> when did he leave?**

_____ / _____
Month *Year*

124. **<u>If your spouse or partner has been deployed,</u> when did he return or when is he expected to return?**

_____ / _____
Month *Year*

125. **How many years of education do you have?**

- ☐ 1 Didn't complete high school
- ☐ 2 Completed high school or GED
- ☐ 3 Vocational or trade school
  - a) **How many years of trade school did you complete?** _____
- ☐ 4 College
  - b) **How many years of college did you complete?** _____
- ☐ 5 Graduate school

126. **Approximately how tall is the father of your new baby?**

_____ *feet* _____ *inches* ☐ 88 DON'T KNOW

127. **Approximately how much does the father of your new baby weigh?**

_____ *pounds* ☐ 88 DON'T KNOW

128. **Would you describe the father of your baby as.....***(check all that apply)*

- ☐ a White
- ☐ b Black/African-American
- ☐ c Hispanic
- ☐ d Latina
- ☐ e Mexican
- ☐ f Cuban
- ☐ g Chinese
- ☐ h Japanese
- ☐ i Filipino
- ☐ k Another Asian ethnicity _____
- ☐ l Native American/Alaskan Native
- ☐ m Another group not listed _____
- ☐ n DON'T KNOW

CONTINUE ON NEXT PAGE →

LAST 4 SSN _ _ _ _ _ FSCID : 6 2 8 _ _ _ _ _ _

TO PROTECT YOUR PRIVACY, THIS PAGE WILL BE SEPARATED FROM THE QUESTIONNAIRE UPON RECEIPT BY ABC STAFF

Would you like a copy of the study results? YES ❑$_1$ NO ❑$_2$

Your Name:

PLEASE COMPLETE YOUR HOME OF RECORD INFORMATION BELOW

Name:	
c/o:	
Street Address:	
City:	
State:	Zip:

ACTIVE DUTY WOMEN CONTINUE BELOW
ALL OTHERS STOP. - Thank You!

ACTIVE DUTY WOMEN ONLY:

My signature below indicates that I did not fill this survey out during working hours as an active personnel.

_____ _____

Signature *Date*

Appendix I: Quality Assurance Recruiter Report and Guidelines

QA RECRUITER REPORT GUIDELINES

The following guidelines define what items are to be observed in each of the categories indicated on the QA Recruiter Report. A QA report should be completed for each recruiter at least twice a week.

(1) Knowledge Of Study

- Explanation of study to respondent is concise and accurate
- Appropriate answers are given to respondent questions
- Neutrality is shown by the recruiter during the enrollment (is this applicable?)

(2) Approach Technique

- Approach at the appropriate time
- Approach appropriate person
- Proper introduction is given
- Recruiter is direct and assertive

(3) Handling Objections

- Advantages of the study are stressed to the respondent
- Recruiter is assertive

(4) Screener - Utilization Of Time

- Time efficiency is shown and eligibility determined promptly
- Recruiter is accurate in gathering information

(5) Consent Form/Record Release - Utilization Of Time

- All main points of consent form are covered with the respondent in a concise and time efficient manner
- Recruiter ensures that the respondent receives a copy of the consent form to take home.

(6) Measurements

- Height is measured correctly and recorded as trained
- Weight is taken correctly and recorded as trained

(7) Closing

- All necessary materials for recruitment are completed and returned. Including screener, questionnaire with accurate measurements, consent form and record release form.
- Recruiter's "take home message" to the respondent is clear. (The respondent is told that she is an ABC mom and on her next visit she needs to fill out a follow-up questionnaire and get weighed. Also if recruited at a visit #1 or 2 she will receive a baseline in the mail when her baby is 2 months old.)

(8) Professionalism/Tone and Demeanor

- Recruiter conveyed enthusiasm about the study.
- Recruiter is polite and focused in communicating the different aspects of the study to the respondent.
- Recruiter has developed a good rapport with the respondent, without engaging in unnecessary side conversations.

(9) Accuracy - Screener

- Recruiter ensures all appropriate information is accurate and the screener is complete.

(10) Accuracy - Consent Form/Record Release

- Recruiter should ensure all the appropriate signatures and dates are on the consent form and that the correct record release form was completed.

QA RECRUITER REPORT

FSCID #: _____

Length: _____

RECRUITER: DATE: TIME:

PROJECT: **628** SUPERVISOR: **RHONDA DITTMAR**

PERFORMANCE RATINGS:

EXCELLENT	**VERY GOOD**	**GOOD**	**FAIR**	**POOR**
5	4	3	2	1

PLEASE RATE:

(1) Knowledge of Study _____

(2) Approach technique _____

(3) Handling objections _____

(4) Screener - Utilization of Time _____

(5) Consent/Release - Utilization of Time _____

(6) Measurements _____

(7) Closing _____

(8) Demeanor _____

(9) Accuracy - Screener _____

(10) Accuracy - Consent/Release _____

OVERALL RATING: _____

FEEDBACK:

_____

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_____ _____

Employee Signature Date

_____ _____

Supervisor Signature Date

RECRUITER COMMENTS:

ADDITIONAL SUPERVISOR COMMENTS: (Please note monitoring category)

Appendix B: Daily Recruiter Tally Sheet